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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

SPECIAL INSPECTOR GENERAL FOR IRAQ RECONSTRUCTION

5 CFR Chapter LXXXII

Supplemental Standards of Ethical Conduct for Employees of the Special Inspector General for Iraq Reconstruction

AGENCY: Special Inspector General for Iraq Reconstruction.

ACTION: Interim rule with request for comments.

SUMMARY: The Special Inspector General for Iraq Reconstruction (SIGIR), with the concurrence of the Office of Government Ethics (OGE), is issuing an interim regulation for employees of the SIGIR that supplement the executive-branch-wide Standards of Ethical Conduct (Standards) issued by OGE. With certain exceptions, this supplemental regulation requires SIGIR employees, except special Government employees, to obtain approval before engaging in outside employment.

DATES: This interim rule is effective June 24, 2010. Written comments must be received by August 23, 2010.

ADDRESSES: Send or deliver comments to Michael H. Mobbs, Deputy General Counsel and Designated Agency Ethics Official, by any of the following methods:

- *E-mail: michael.mobbs@sigir.mil* Include the reference "SIGIR Supplemental Standards" in the subject line of the message.
- *Fax:* 703–428–0817.
- *Mail/Hand Delivery/Courier:* SIGIR, 400 Army Navy Drive, Arlington, VA 22202–4704, Attention: Michael H. Mobbs, Deputy General Counsel and Designated Agency Ethics Official (DAEO).

FOR FURTHER INFORMATION CONTACT: Michael H. Mobbs, Deputy General Counsel, Telephone 703–604–0429; e-mail: *michael.mobbs@sigir.mil.*

SUPPLEMENTARY INFORMATION:

Background

In 1992, OGE published Standards of Ethical Conduct for Employees of the Executive Branch (Standards) which became effective on February 3, 1993. The Standards, as corrected and amended, are codified at 5 CFR part 2635. The Standards set uniform ethical conduct standards applicable to all executive branch personnel. Section 2635.105 of the Standards authorizes agencies, with the concurrence of OGE, to publish agency-specific supplemental regulations that are necessary to properly implement their respective ethics programs. The SIGIR, with OGE's concurrence, has determined that the following interim supplemental rule is necessary for successful implementation of its ethics program.

Analysis of the Regulations

Section 9201.101 General

Section 9201.101 explains that the regulations in part 9201 apply to employees of the SIGIR and supplement the OGE Standards. This section also includes cross-references to other issuances applicable to SIGIR employees, including the regulations concerning executive branch financial disclosure, financial interests, and employee responsibilities and conduct, as well as implementing SIGIR guidance and procedures issued in accordance with OGE Standards.

Section 9201.102 Prior Approval for Outside Employment and Other Outside Activities

In accordance with 5 CFR 2635.803, the SIGIR has determined it is necessary for the purpose of administering its ethics program to require its employees to obtain approval before engaging in outside employment or activities. This approval requirement will help to ensure that potential ethical problems are resolved before employees begin outside employment or activities that could involve a violation of applicable statutes and standards of conduct.

Section 9201.102(a) provides that a SIGIR employee, other than a special Government employee, must obtain advance written approval from the employee's supervisor and the concurrence of the Designated Agency Ethics Official (DAEO) or alternate DAEO before engaging in any outside employment except to the extent that the SIGIR DAEO or alternate DAEO has issued an instruction or manual pursuant to paragraph (e) of this section exempting an activity or class of activities from this requirement.

Section 9201.102(b) broadly defines outside employment to cover any form of non-Federal employment or business relationship involving the provision of personal services, whether or not for compensation, other than the discharge of official duties. It includes writing when done under an arrangement with another person or entry for production or publication of the written product. It does not, however, include participation in the activities of non-profit charitable, religious, professional, social, fraternal, educational, recreational, public service, or civic organizations, unless such activities are for compensation other than reimbursement of expense, the organization's activities are devoted substantially to matters relating to the employee's official duties as defined in 5 CFR 2635.807(a)(2)(i)(B) through (E) and the employee will serve as an officer or director of the organization, or the activities will involve the provision of consultative or professional services. Consultative services means the provision of personal services by an employee, including the rendering of advice or consultation, which requires advanced knowledge in a field of science or learning customarily acquired by a course of specialized instruction and study in an institution of higher education, hospital, or similar facility. Professional services means the provision of personal services by an employee, including the rendering of advice or consultation, which involves application of the skills of a profession as defined in 5 CFR 2636.305(b)(1) or involves a fiduciary relationship as defined in 5 CFR 2636.305(b)(2). A note following paragraph (b) of § 9201.102 pertains to the special approval requirement set out in both 18 U.S.C. 203(d) and 205(e) respectively, for certain representational activities otherwise covered by the conflict of interest restrictions on compensation and activities of employees in claims against and other matters affecting the Government. The note explains that an employee who wishes to act as agent or attorney for, or otherwise represent his parents, spouse, child, or any person for whom, or any estate for which, he is

serving as guardian, executor, administrator, trustee or other personal fiduciary in such matters must obtain the approval required by law of the Government official responsible for the employee's appointment in addition to the regulatory approval required in § 9201.102.

Section 9201.102(c) sets out the procedures for requesting prior approval to engage in outside employment initially, or within seven calendar days of a significant change in the nature or scope of the outside employment or the employee's official position.

Section 9201.102(d) sets out the standard to be applied by the employee's supervisor and the DAEO or alternate DAEO in acting on requests for prior approval of outside employment as broadly defined by 9201.102(b). Approval shall be granted only upon a determination that the outside employment is not expected to involve conduct prohibited by statute or Federal regulation, including 5 CFR part 2635.

Section 9201.102(e) provides that the SIGIR DAEO or alternate DAEO can issue instructions or manual issuances governing the submission of requests for approval of outside employment, which may exempt categories of employment from the prior approval requirement of this section based on a determination that employment within those categories would generally be approved and is not likely to involve conduct prohibited by statute or Federal regulation, including 5 CFR part 2635. The instructions or issuances may include examples of outside employment that are permissible or impermissible consistent with this part and 5 CFR part 2635.

Administrative Procedure Act

Pursuant to 5 U.S.C. 553(b) the SIGIR finds good cause exists for waiving the general notice of proposed rulemaking and opportunity for public comment as to this interim rule.

Notice and comment before the effective date are being waived because this rule concerns matters of agency organization, practice and procedure. However, written comments, which must be received by August 23, 2010, can be submitted on this interim rule; any such comments will be considered before this rule is adopted as final.

Executive Orders 12866 and 12988

Because this rule relates to SIGIR personnel, it is exempt from the provisions of Executive Orders Nos. 12866 and 12988.

Regulatory Flexibility Act

SIGIR has determined, pursuant to the Regulatory Flexibility Act, 5 U.S.C. chapter 6, that this rulemaking will not have a significant economic impact on a substantial number of small entities because it primarily affects SIGIR employees.

Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. chapter 35, does not apply because this rulemaking does not contain information collection requirements subject to the approval of the Office of Management and Budget.

Congressional Review Act

SIGIR has determined that this rule is not a rule as defined in 5 U.S.C. 804, and thus, does not require review by Congress.

List of Subjects in 5 CFR Part 9201

Conflict of interest, Government employees.

■ Accordingly, for the reasons set forth in the preamble, the Special Inspector General for Iraq Reconstruction, with the concurrence of the Office of Government Ethics, is amending title 5 of the Code of Federal Regulations by adding a new chapter LXXXII, consisting of part 9201, to read as follows:

Chapter LXXXII—Special Inspector General for Iraq Reconstruction

PART 9201—SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE SPECIAL INSPECTOR GENERAL FOR IRAQ RECONSTRUCTION

Sec.
9201.101 General.
9201.102 Prior approval for outside employment and other outside activities.

Authority: 5 U.S.C. 7301; 5 U.S.C. App. (Ethics in Government Act of 1978); E.O. 12674, 54 FR 15159; 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547; 3 CFR, 1990 Comp., p. 306; 5 CFR 2635.105, 2635.802, 2635.803, 2635.807.

§ 9201.101 General.

(a) *Purpose.* In accordance with 5 CFR 2635.105, the regulations in this part apply to employees of the Special Inspector General for Iraq Reconstruction (SIGIR) and supplement the Standards of Ethical Conduct for Employees of the Executive Branch contained in 5 CFR part 2635.

(b) *Cross-references.* In addition to 5 CFR part 2635 and this part, SIGIR employees are required to comply with implementing guidance and procedures issued by SIGIR in accordance with 5 CFR 2635.105(c). SIGIR employees are also subject to the regulations concerning executive branch financial disclosure contained in 5 CFR part 2634, the regulations concerning executive branch financial interests contained in 5 CFR part 2640, and the regulations concerning executive branch employee responsibilities and conduct contained in 5 CFR part 735.

§ 9201.102 Prior approval for outside employment and other outside activities.

(a) *General requirement.* Before engaging in any outside employment, with or without compensation, an employee of the SIGIR, other than a special Government employee, must obtain written approval from the employee's supervisor and the concurrence of the Designated Agency Ethics Official (DAEO) or the alternate DAEO, except to the extent that the SIGIR DAEO or alternate DAEO has issued an instruction or manual pursuant to paragraph (e) of this section exempting an activity or class of activities from this requirement. Nonetheless, special Government employees remain subject to other statutory and regulatory provisions governing their outside activities, including 18 U.S.C. 203(c) and 205(c), as well as applicable provisions of 5 CFR part 2635.

(b) *Definition of employment.* For purposes of this section, employment means any form of non-Federal employment or business relationship involving the provision of personal services, whether or not for compensation. It includes, but is not limited to, services as an officer, director, employee, agent, advisor, attorney, consultant, contractor, general partner, trustee, teacher, or speaker. It includes writing when done under an arrangement with another person for production or publication of the written product. The definition does not include participation in the activities of a nonprofit charitable, religious, professional, social, fraternal, educational, recreational, public service, or civic organization, unless:

(1) The employee will receive compensation other than reimbursement of expenses;

(2) The organization's activities are devoted substantially to matters relating to the employee's official duties as defined in 5 CFR 2635.807(a)(2)(i)(B) through (E) and the employee will serve as officer or director of the organization; or

(3) The activities will involve the provision of consultative or professional services. *Consultative services* means the provision of personal services by an

employee, including the rendering of advice or consultation, which requires advanced knowledge in a field of science or learning customarily acquired by a course of specialized instruction and study in an institution of higher education, hospital or similar facility. *Professional services* means the provision of personal service by an employee, including the rendering of advice or consultation, which involves application of the skills of a profession as defined in 5 CFR 2636.305(b)(1) or involves a fiduciary relationship as defined in 5 CFR 2636.305(b)(2).

Note to § 9201.102(b): There is a special approval requirement set out in both 18 U.S.C. 203(d) and 205(e) respectively, for certain representational activities otherwise covered by the conflict of interest restrictions on compensation and activities of employees in claims against and other matters affecting the Government. Thus, an employee who wishes to act as agent or attorney for, or otherwise represent his parents, spouse, child, or any person for whom, or any estate for which, he is serving as guardian, executor, administrator, trustee, or other personal fiduciary in such matters must obtain the approval required by law of the Government official responsible for the employee's appointment in addition to the regulatory approval required by this section.

(c) *Procedure for requesting approval.* (1) The approval required by paragraph (a) of this section shall be requested by e-mail or other form of written correspondence at least 30 calendar days in advance of engaging in outside employment as defined in paragraph (b) of this section.

(2) The request for approval to engage in outside employment or certain other activities shall set forth, at a minimum:

(i) The name of the employer or organization;

(ii) The nature of the legal activity or other work to be performed;

(iii) The title of the position; and

(iv) The estimated duration of the outside employment.

(3) Upon a significant change in the nature or scope of the outside employment or in the employee's official position within the SIGIR, the employee must, within 7 calendar days of the change, submit a revised request for approval.

(d) *Standard for approval.* Approval shall be granted only upon a determination that the outside employment is not expected to involve conduct prohibited by statute or Federal regulation, including 5 CFR part 2635.

(e) *DAEO's and alternate DAEO's responsibilities.* The SIGIR DAEO or alternate DAEO may issue instructions or manual issuances governing the submission of requests for approval for outside employment. The instructions or manual issuances may exempt categories of employment from the prior approval requirement of this section based on a determination that employment within those categories of employment would generally be approved and is not likely to involve conduct prohibited by statute or Federal regulation, including 5 CFR part 2635. The DAEO or alternate DAEO may include in these instructions or issuances examples of outside employment that are permissible or impermissible consistent with this part and 5 CFR 2635.

Stuart W. Bowen, Jr.,

Special Inspector General for Iraq Reconstruction.

Approved: June 10, 2010.

Robert I. Cusick,

Director, Office of Government Ethics.

[FR Doc. 2010–15103 Filed 6–23–10; 8:45 am]

BILLING CODE 3710–8N–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 989

[Doc. No. AMS–FV–09–0075; FV10–989–1 FIR]

Raisins Produced From Grapes Grown in California; Final Free and Reserve Percentages for 2009–10 Crop Natural (Sun-Dried) Seedless Raisins

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: The Department of Agriculture (USDA) is adopting, as a final rule, without change, an interim rule that established final volume regulation percentages of 85 percent free and 15 percent reserve for the 2009–10 crop of Natural (sun-dried) Seedless (NS) raisins covered under the Federal marketing order for California raisins (order). The percentages are intended to help stabilize raisin supplies and prices, and strengthen market conditions.

DATES: Effective June 25, 2010. The volume regulation percentages apply to acquisitions of NS raisins from the 2009–10 crop until the reserve raisins from that crop are disposed of under the marketing order.

FOR FURTHER INFORMATION CONTACT: Terry Vawter, Senior Marketing Specialist, or Kurt J. Kimmel, Regional Manager, California Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA; Telephone: (559) 487–5901; Fax: (559) 487–5906; or E-mail: *Terry.Vawter@ams.usda.gov* or *Kurt.Kimmel@ams.usda.gov.*

Small businesses may obtain information on complying with this and other marketing order regulations by viewing a guide at the following Web site: *http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&page=MarketingOrdersSmallBusinessGuide;* or by contacting Antoinette Carter, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491; Fax: (202) 720–8938; or E-mail: *Antoinette.Carter@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement and Order No. 989, both as amended (7 CFR part 989), regulating the handling of raisins produced from grapes grown in California, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the "Act."

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

The handling of California raisins is regulated by 7 CFR part 989. The order authorizes the establishment of volume regulations, when warranted, for each crop. Volume regulations: (1) Help the industry address its marketing problems by keeping supplies in balance with demand; (2) strengthen market conditions; (3) fully supply both the domestic and export markets without overburdening them; and (4) provide for market expansion.

Volume regulation is warranted for the 2009–10 crop of NS raisins because the crop estimate (supply) exceeded the trade demand (demand). In an interim rule published in the **Federal Register** on April 22, 2010, and effective on April 23, 2010 (75 FR 20897; Doc No. AMS–FV–09–0075, FV10–989–1 IFR), § 989.257 was amended by incorporating the 2009–10 crop year final free and reserve percentages. This rule continues in effect the rule that established a final free percentage of 85 percent, and a final reserve percentage of 15 percent, of NS raisins acquired by handlers during the crop year, which began August 1, 2009, and ends July 31, 2010.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural

Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 26 handlers of California raisins who are subject to regulation under the order and approximately 3,000 raisin producers in the regulated area. Small agricultural service firms are defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than $7,000,000, and small agricultural producers as those having annual receipts of less than $750,000. Approximately 18 handlers and a majority of producers of California raisins may be classified as small entities.

Since 1949, the California raisin industry has operated under a Federal marketing order. The order contains authority to limit the portion of a given year's crop that can be marketed freely in any outlet by raisin handlers. This volume regulation mechanism is used to stabilize supplies and prices, and to strengthen market conditions. If the primary market (the normal domestic market) is over-supplied with raisins, grower prices decline substantially.

Pursuant to § 989.54(d) of the order, this rule establishes final volume regulation percentages for the 2009–10 crop year for NS raisins. The volume regulation percentages are 85 percent free and 15 percent reserve. Free tonnage raisins may be sold by handlers to any market. Reserve raisins must be held in a pool for the account of the committee and are disposed of through certain programs authorized under the order. Volume regulation is warranted this season because the crop estimate of 275,000 tons is significantly higher than the 234,769 ton trade demand.

The volume regulation procedures have helped the industry address its marketing problems by keeping supplies in balance with domestic and export market needs, and strengthening market conditions. The volume regulation procedures fully supply the domestic and export markets, provide for market expansion, and help reduce the burden of oversupplies in the domestic market.

Raisin grapes are a perennial crop, so production in any year is dependent upon plantings made in earlier years. The sun-drying method of producing raisins involves considerable risk because of variable weather patterns.

Even though the product and the industry are viewed as mature, the industry has experienced considerable change over the last several decades. Before the 1975–76 crop year, more than 50 percent of the raisins were packed and sold directly to consumers. Now, about 63 percent of the raisins are sold in bulk. This means that raisins are now sold to consumers mostly as an ingredient in another product such as cereal and baked goods. In addition, for a few years in the early 1970s, over 50 percent of the raisin grapes were sold fresh to the wine market for crushing. Since then, the percent of raisin-variety grapes sold to the wine industry has decreased.

California's grapes are classified into three groups—table grapes, wine grapes, and raisin-variety grapes. Raisin-variety grapes are the most versatile of the three types. They can be marketed as fresh grapes, crushed for juice in the production of wine or juice concentrate, or dried into raisins. Annual fluctuations in the fresh grape, wine, and concentrate markets, as well as weather-related factors, cause fluctuations in raisin supply. This type of situation introduces a certain amount of variability into the raisin market. These fluctuations can result in producer price instability and disorderly market conditions.

Volume regulation is helpful to the raisin industry because it lessens the impact of such fluctuations and contributes to orderly marketing. For example, producer prices for NS raisins remained fairly steady between the 1993–94 and 1997–98 crop years, although production varied. As shown in the table below, during those years, production varied from a low of 272,063 tons in 1996–97 to a high of 387,007 tons in 1993–94.

According to committee data, the total producer return per ton during those years, which includes proceeds from both free tonnage plus reserve pool raisins, has varied from a low of $904.60 in 1993–94 to a high of $1,049.20 in 1996–97. Producer prices for the 1998–99 and 1999–2000 crop years increased significantly due to back-to-back short crops during those years. Record large crops followed, and producer prices dropped dramatically for the 2000–01 through 2003–04 crop years, as inventories grew while demand stagnated. However, as noted below, producer prices were higher for the 2004–05 through 2008–09 crop years:

NATURAL SEEDLESS (NATURAL CONDITION) DELIVERIES, FIELD PRICES AND PRODUCER PRICES

Crop year	Deliveries (tons)	Field prices (per ton)[1]	Producer prices (per ton)
2008–09	364,268	$1,310.00	[2] $1,139.70
2007–08	329,288	1,210.00	[2] 1,028.50
2006–07	282,999	1,210.00	[1] 1,089.00
2005–06	319,126	1,210.00	[1] 998.25
2004–05	265,262	1,210.00	[3] 1,210.00
2003–04	296,864	810.00	567.00
2002–03	388,010	745.00	491.20
2001–02	377,328	880.00	650.94
2000–01	432,616	877.50	603.36
1999–2000	299,910	1,425.00	1,211.25
1998–99	240,469	1,290.00	[3] 1,290.00
1997–98	382,448	1,250.00	946.52
1996–97	272,063	1,220.00	1,049.20
1995–96	325,911	1,160.00	1,007.19
1994–95	378,427	1,160.00	928.27
1993–94	387,007	1,155.00	904.60

[1] Field prices for NS raisins are established by the Raisin Bargaining Association, and are also referred to in the industry as the "free tonnage price" for raisins.

[2] Return-to-date, reserve pool still open.
[3] No volume regulation.

There are essentially two broad markets for raisins—domestic and export. Domestic shipments generally increased over the years. Although domestic shipments decreased from a high of 204,805 packed tons during the 1990–91 crop year to a low of 156,325 packed tons in 1999–2000, they increased from 174,117 packed tons during the 2000–01 crop year to 193,609 packed tons during the 2007–08 crop year and decreased to 191,929 packed tons during the 2008–09 crop year. Export shipments ranged from a high of 107,931 packed tons in the 1991–92 crop year to a low of 91,599 packed tons in the 1999–2000 crop year. Since that time, export shipments increased to 106,755 tons of raisins during the 2004–05 crop year, fell to 101,684 tons in the 2006–07 crop year, and again increased to 142,541 tons in the 2007–08 crop year. This significant increase was due to a short crop in Turkey. Export shipments remained relatively high in 2008–09 at 125,789 tons.

The per capita consumption of raisins has declined from 2.07 pounds in 1988 to 1.46 pounds in 2007. This decrease is consistent with the decrease in the per capita consumption of dried fruits in general, which may be due to the increasing year-round availability of most types of fresh fruit.

While the overall demand for raisins has increased in four of the last five years (as reflected in increased commercial shipments), production has been decreasing. Deliveries of NS dried raisins from producers to handlers reached an all-time high of 432,616 tons in the 2000–01 crop year. This large crop was preceded by two short crop years; deliveries were 240,469 tons in the 1998–99 crop year and 299,910 tons in the 1999–2000 crop year. Deliveries for the 2000–01 crop year soared to a record level because of increased bearing acreage and yields. Deliveries for the 2001–02 crop year were at 377,328 tons, 388,010 tons for the 2002–03 crop year, 296,864 tons for the 2003–04 crop year, and 265,262 tons for the 2004–05 crop year.

After three crop years of high production and a large 2001–02 carry-in inventory, the industry diverted raisin production to other uses or removed bearing vines. Diversions/removals totaled 38,000 acres in 2001; 27,000 acres in 2002; and 8,000 acres of vines in 2003. These actions resulted in declining deliveries of 296,864 tons for the 2003–04 crop year and 265,262 tons for the 2004–05 crop year. Although deliveries increased in 2005–06 crop year to 319,126 tons, this may have been because fewer growers opted to contract with wineries, as raisin variety grapes crushed in 2005–06 crop year decreased by 161,000 green tons, the equivalent of over 40,000 tons of raisins. In the 2006–07 crop year, raisin deliveries were again less than 300,000 tons at 282,999 tons and increased to 329,288 tons in 2007–08 crop year. The 2008–09 crop year was considered to be a good crop and the quality of the crop has a direct bearing on the overall production with 364,268 tons of NS raisins delivered.

The order permits the industry to exercise volume regulation provisions, which allow for the establishment of free and reserve percentages, and establishment of a reserve pool. One of the primary purposes of establishing free and reserve percentages is to balance supply and demand. If raisin markets are over-supplied with product, producer prices will decline.

Raisins are generally marketed at relatively lower price levels in the more elastic export market than in the more inelastic domestic market. This results in a larger volume of raisins being marketed and enhances producer returns. In addition, this system allows the U.S. raisin industry to be more competitive in export markets.

The reserve percentage limits provides for raisins that handlers can market as free tonnage. Based on the 2009–10 crop year estimate of 275,000 tons, the 15 percent reserve would limit the total free tonnage to 233,750 natural condition tons (0.85 x the 275,000 ton crop). Adding the estimated figure of 41,250 tons of raisins offered to handlers through the 10 + 10 program to the 233,750 tons of free tonnage, plus 126,824 tons of carry-in inventory, plus 12,137 tons of 2008–09 NS reserve pool raisins released during the 2009–10 crop year, results in a total supply of 413,961 tons of natural condition raisins.

With volume regulation, producer prices are expected to be higher than without volume regulation. This price increase is beneficial to all producers regardless of size, and enhances producers' total revenues in comparison to no volume regulation. Establishing a reserve allows the industry to help stabilize supplies in both domestic and export markets, while improving returns to producers.

Free and reserve percentages are established by varietal type; and are generally established in years when the supply exceeds the trade demand by a large enough margin that the committee believes volume regulation is necessary to maintain market stability. Accordingly, in assessing whether to apply volume regulation or, as an alternative, not to apply such regulation, the committee determined that volume regulation was warranted for the 2009–10 crop for only one of the nine raisin varietal types defined under the order.

The free and reserve percentages established in the interim rule release the full trade demand and apply uniformly to all handlers in the industry, regardless of size. For NS raisins, with the exception of the 1998–99 and 2004–05 crop years, small and large raisin producers and handlers have been operating under volume regulation percentages every year since the 1983–84 crop year. There are no known additional costs incurred by small handlers that are not incurred by large handlers. While the level of benefits of this rulemaking are difficult to quantify, the stabilizing effects of the volume regulations impact small and large handlers positively by helping them maintain and expand markets even though raisin supplies fluctuate widely from season to season. Likewise, price stability positively impacts small and large producers by allowing them to better anticipate the revenues their raisins will generate.

This rule continues in effect the action that established final volume regulation percentages for the 2009–10 crop year for NS raisins at 85 percent free and 15 percent reserve. The volume regulation percentages are intended to help stabilize raisin supplies and prices, meet the needs of the domestic and export markets, strengthen market conditions, and expand marketing opportunities.

This rule will not impose any additional reporting or recordkeeping requirements on either small or large raisin handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. In addition, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

Further, the committee meeting on October 6, 2009, at which this recommendation was made, was widely publicized throughout the raisin industry, and all interested persons were invited to attend the meeting and encouraged to participate in the

committee's deliberations. Like all committee meetings, the meeting was a public meeting; and all entities, both large and small, were able to express their views on this issue.

Comments on the interim rule were required to be received by May 24, 2010. One comment supporting the rule was received. Therefore, for the reasons given in the interim rule, we are adopting the interim rule as a final rule, without change.

To view the interim rule, go to: *http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480add0ad.*

This action also affirms information contained in the interim rule concerning Executive Orders 12866 and 12988, the Paperwork Reduction Act (44 U.S.C. Chapter 35), and the E–Gov Act (44 U.S.C. 101).

After consideration of all relevant material presented, it is found that finalizing the interim rule without change, as published in the **Federal Register** (75 FR 20897, April 22, 2010), will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 989

Grapes, Marketing agreements, Raisins, Reporting and recordkeeping requirements.

PART 989—[AMENDED]

■ Accordingly, the interim rule that amended 7 CFR part 989 and that was published at 75 FR 20897 on April 22, 2010, is adopted as a final rule, without change.

Dated: June 18, 2010.

Robert C. Keeney,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2010–15298 Filed 6–23–10; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Part 1774

RIN 0572–AC14

Special Evaluation Assistance for Rural Communities and Households Program

ACTION: Final rule.

SUMMARY: The Rural Utilities Service (RUS) is issuing a regulation to establish the Special Evaluation Assistance for Rural Communities and Households (SEARCH) Program as authorized by Section 306(a)(2) of the Consolidated Farm and Rural Development Act (CONACT) (7 U.S.C. 1926(a)(2)). The amendment added the new SEARCH grant program under which the Secretary is authorized to make predevelopment planning grants for feasibility studies, design assistance, and technical assistance to financially distressed communities in rural areas with populations of 2,500 or fewer inhabitants for water and waste disposal projects.

DATES: This rule is effective June 24, 2010.

FOR FURTHER INFORMATION CONTACT: Anita O'Brien, Loan Specialist, Water and Environmental Programs, U.S. Department of Agriculture, Rural Utilities Service, Room 2230 South Building, Stop 1570, 1400 Independence Ave., SW., Washington, DC 20250–1570. Telephone: (202) 690–3789, FAX: (202) 690–0649, E-mail: *anita.obrien@usda.gov.*

SUPPLEMENTARY INFORMATION:

Classification

Executive Order 12866

This final rule has been determined to be not significant for purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988

This final rule has been reviewed in accordance with Executive Order 12988, Civil Justice Reform. RUS has determined that this final rule meets the applicable standards provided in section 3 of the Executive Order. In addition, all State and local laws and regulations that are in conflict with this rule will be pre-empted; no retroactive effect will be given to the rule; and in accordance with sec. 212(e) of the Department of Agriculture Reorganization Act of 1994 (7 U.S.C. sec. 6912(e)), appeal procedures must be exhausted before an action against the Department or its agencies may be initiated.

Regulatory Flexibility Act Certification

RUS has determined that this final rule will not have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The RUS Water and Environmental Programs provide loans to borrowers at interest rates and terms that are more favorable than those generally available from the private sector. RUS borrowers, as a result of obtaining Federal financing, receive economic benefits that exceed any direct economic costs associated with complying with RUS regulations and requirements.

Information Collection and Recordkeeping Requirements

The information collection and recordkeeping requirements contained in this final rule are pending approval by OMB pursuant to the Paperwork Reduction Act 1995 (44 U.S.C. Chapter 35) under control number 0572—New. The paperwork contained in this rule will not be effective until approved by OMB.

E-Government Act Compliance

The Rural Utilities Service is committed to the E-Government Act, which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

National Environmental Policy Act Certification

The Administrator of RUS has determined that this final rule will not significantly affect the quality of the human environment as defined by the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*). Therefore, this action does not require an environmental impact statement or assessment.

Catalog of Federal Domestic Assistance

The program described by this final rule is listed in the Catalog of Federal Domestic Assistance Programs under number 10.759—Special Evaluation Assistance for Rural Communities and Households Program (SEARCH). This catalog is available on a subscription basis from the Superintendent of Documents, the United States Government Printing Office, Washington, DC, 20402–9325, telephone number (202) 512–1800 and at *https://www.cfda.gov.*

Executive Order 12372

This program is not subject to the requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs," as implemented under USDA's regulations at 7 CFR part 3015.

Unfunded Mandates

This final rule contains no Federal mandates (under the regulatory provision of title II of the Unfunded Mandates Reform Act of 1995) for State, local, and Tribal governments or the private sector. Therefore, this final rule is not subject to the requirements of section 202 and 205 of the Unfunded Mandates Reform Act.

Executive Order 13132, Federalism

The policies contained in this final rule do not have any substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Nor does this final rule impose substantial direct compliance costs on State and local governments. Therefore, consultation with States is not required.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

USDA will undertake, within 6 months after this rule becomes effective, a series of regulation Tribal consultation sessions to gain input by Tribal officials concerning the impact of this rule on Tribal governments, communities, and individuals. These sessions will establish a baseline of consultation for future actions, should any become necessary, regarding this rule. Reports from these sessions for consultation will be made part of the USDA annual reporting on Tribal Consultation and Collaboration. USDA will respond in a timely and meaningful manner to all Tribal government requests for consultation concerning this rule and will provide additional venues, such as webinars and teleconferences, to periodically host collaborative conversations with Tribal leaders and their representatives concerning ways to improve this rule in Indian country.

Background

On January 22, 2010, RUS published a proposed rule in the **Federal Register** (75 FR 3642) to establish the Special Evaluation Assistance for Rural Communities and Households (SEARCH) Program as authorized by Section 306(a)(2) of the Consolidated Farm and Rural Development Act (CONACT) (7 U.S.C. 1926(a)(2)). The amendment added a grant program to make Special Evaluation Assistance for Rural Communities and Households (SEARCH) Program grants. SEARCH grants are intended to assist financially distressed, eligible communities to pay for feasibility studies, design assistance and technical assistance associated with water and waste disposal infrastructure needs.

Under the SEARCH program, the Secretary may make predevelopment and planning grants to public or quasi-public agencies, organizations operated on a not-for-profit basis or Indian Tribes on Federal and State reservations and other Federally recognized Indian Tribes. Up to 100 percent of the eligible cost of the grant may be funded and may not exceed $30,000. The grant recipients shall use the grant funds for feasibility studies, design assistance, and development of an application for financial assistance to financially distressed communities in rural areas with populations of 2,500 or fewer inhabitants for water and waste disposal projects as authorized in Sections 306(a)(1), 306(a)(2) and 306(a)(24) of the Consolidated Farm and Rural Development Act (CONACT) (7 U.S.C. 1926(a)(1), (a)(2) and (a)(24).

Eligible entities for the SEARCH grants will be the same entities eligible to obtain a loan, grant, or loan guarantee from the Rural Utilities Service Water and Waste Disposal and Wastewater loan and grant programs. However, as applied to the SEARCH program, rural area is specified as one with a population of 2,500 or less. The Agency will define financially distressed areas as those where the median household income of the areas to be served is either below the poverty line or below 80 percent of the statewide non-metropolitan median household income.

The Secretary may use not more than four percent of the total amount of funds made available for a fiscal year for water and waste disposal to carry out the SEARCH program.

The Administrator of the RUS is required to prescribe regulations to implement the provisions of the SEARCH grant program and does so through this final rule. In developing the SEARCH program regulation, the Agency relied heavily on existing Rural Development regulations relative to water and waste disposal loans and grants.

Comments

RUS published a proposed rulemaking in the **Federal Register** on January 22, 2010 at 75 FR 3642. No comments were received from outside Federal agencies, however, one public submission was received with regard to the information collection and recordkeeping requirements contained in the rule. The commentor's responses are summarized below with the Agency's response as follows:

Issue 1: Commentor agreed that the collection is necessary for performance and practical utility.

Response: Agency concurs.

Issue 2: Commentor agreed that the burden estimate is accurate.

Response: Agency concurs.

Issue 3: Commentor suggested that the information quality, utility and clarity could be enhanced by allowing extra application credit for professional services; reporting the status of applicable Federal property management specifications on the RUS Web site; adding available water management references to the RUS Web site as a component of the design and technical assistance object; and expounding upon the definition of rural.

Response: The Agency will take under advisement the suggestion to provide additional information on RUS Web site. For the purpose of water and waste disposal grants and direct and guaranteed loans, the terms "rural" and "rural area" mean a city, town, or unicorporated area that has a population of no more than 10,000 inhabitants (7 U.S.C. 1991(a)(13). The SEARCH grant amendment (7 U.S.C. (a)(2)(c)) restricts eligibility, for the purposes of SEARCH, to communities of 2,500 or less within such rural areas.

Issue 4: Commentor suggested the collection burden can be minimized by adding two rural support offices directly to the Web pages.

Response: The Agency believes that there is minimal burden with the current Web site in obtaining States' local office information.

List of Subjects

Community development, Grant programs, Reporting and recordkeeping requirements, Rural areas, Waste treatment and disposal, Water supply.

■ Therefore for the reasons discussed in the preamble, RUS amends chapter XVII of title 7 of the Code of Federal Regulations by adding a new part 1774 to read as follows:

PART 1774—SPECIAL EVALUATION ASSISTANCE FOR RURAL COMMUNITIES AND HOUSEHOLDS PROGRAM (SEARCH)

Subpart A—General Provisions

1774.1 General.
1774.2 Definitions.
1774.3 Availability of forms and regulations.
1774.4 Allocation of funds.
1774.5–1774.6 [Reserved]
1774.6 Equal opportunity requirements.
1774.7 Environmental requirements.
1774.8 Other Federal Statutes.
1774.9 [Reserved]

Subpart B—Grant Application Processing

1774.10 Applications.
1774.11 [Reserved]
1774.12 Eligibility.
1774.13 Limitations.
1774.14 Eligible grant purposes.
1774.15 Selection criteria.
1774.16 Grant application processing and approval.
1774.17 Grant closing and disbursement.
1774.18 Reporting requirements, accounting methods and audits.

1774.19 Applications determined ineligible.
1774.20 Conflict of Interest.
1774.21–1774.23 [Reserved]
1774.24 Exception Authority.
1774.25–1774.99 [Reserved]
1774.100 OMB Control Number.

Authority: 7 U.S.C. 1926(a)(2)(C).

Subpart A—General Provisions

§ 1774.1 General.

The purpose of the Special Evaluation Assistance for Rural Communities and Household (SEARCH) Grant program is to provide financial assistance to the neediest, eligible communities, who lack financial resources to pay for feasibility studies, design assistance and technical assistance. This subpart sets forth the general policies and procedures for making and processing predevelopment planning SEARCH grants for water and waste projects.

§ 1774.2 Definitions.

The following definitions apply to subparts A and B of this part.

Agency. The Rural Utilities Service of the United States Department of Agriculture (USDA) within the Rural Development mission area of the Under Secretary for Rural Development. The Processing Official will administer this water and waste program on behalf of the Rural Utilities Service.

Approval official. The Agency official at the State level who has been delegated the authority to approve grants.

ConAct. Consolidated Farm and Rural Development Act (7 U.S.C. 1926(a)(2)).

Design assistance. Preliminary design and engineering analysis necessary for an application for funding. Design assistance does not include financial assistance for development of plans, specifications, or bidding documents.

DUNS Number. Data Universal Numbering System number obtained from Dun and Bradstreet and used when applying for Federal grants or cooperative agreements. A DUNS number may be obtained at no cost, by calling 1–866–705–5711.

Eligible entity. Entity that meets eligibility requirements to obtain a loan, loan guarantee or grant under Paragraphs 1, 2 or 24 of Section 306(a) of the ConAct (codified at 7 U.S.C. Section 1926(a)(1)(2) and (24)).

Feasibility study. Documentation associated with an objective analysis of project-related technical engineering or environmental impact analyses required to support applications for funding water or waste disposal projects through USDA, Rural Utilities Service or other agencies.

Financially distressed area. An area is considered financially distressed if the median household income of the area to be served is either below the poverty line or below 80 percent of the statewide non-metropolitan median household income based on available historic statistical information from the latest decennial census.

Grantee. The applicant receiving financial assistance directly from the RUS to carry out the project or program under this program.

Poverty line. The level of income for a family of four, as defined in section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)).

Processing Official. The Agency official designated by the approval official as having the authority to accept and process applications for water and waste disposal assistance.

Rural area. For the purposes of this SEARCH program, any area not in a city or town with a population of 2,500 or fewer, according to the latest decennial census of the United States.

State. Any of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Territory of Guam, the Commonwealth of the Northern Mariana Islands, the Republic of the Marshall Islands, the Federated States of Micronesia, the Republic of Palau, and the U.S. Virgin Islands.

Technical Assistance. Supervision, oversight, or training by an organization for the development of an application for financial assistance.

§ 1774.3 Availability of forms and regulations.

Information about the forms, instructions, regulations, bulletins, OMB Circulars, Treasury Circulars, standards, documents and publications cited in this part is available from any UDSA/Rural Development Office or the United States Department of Agriculture, Washington, DC 20250–1500 and at *http://www.grants.gov.*

§ 1774.4 Allocation of funds.

The Secretary may use not more than four percent of the total amount of funds made available for a fiscal year for water and waste disposal activities for SEARCH grants.

§§ 1774.5–1774.6 [Reserved]

§ 1774.7 Environmental requirements.

The policies and regulations contained in 7 CFR part 1794 of this title apply to grants made in accordance with this part.

§ 1774.8 Other Federal Statutes.

Other Federal statutes and regulations are applicable to grants awarded under this part. These include but are not limited to:

(a) 7 CFR part 1, subpart A—USDA implementation of Freedom of Information Act.

(b) 7 CFR part 3—USDA implementation of OMB Circular No. A–129 regarding debt collection.

(c) 7 CFR part 15, subpart A—USDA implementation of Title VI of the Civil Rights Act of 1964, as amended.

(d) 7 CFR part 1794, RUS Implementation of the National Environmental Policy Act.

(e) 7 CFR part 1901, subpart E—Civil Rights Compliance Requirements.

(f) 7 CFR part 3015—Uniform Federal Assistance Regulations.

(g) 7 CFR part 3016—USDA Implementation of OMB Circular Nos. A–102 and A–97, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.

(h) 7 CFR part 3018—Restrictions on Lobbying, prohibiting the use of appropriated funds to influence Congress or a Federal agency in connection with the making of any Federal grant and other Federal contracting and financial transactions.

(i) 7 CFR part 3019—USDA implementation of OMB Circular A–110, Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.

(j) 7 CFR part 3021, as amended—Government-wide Debarment and Suspension (Non-procurement); Government-wide Requirements for Drug-Free Workplace (Grants), implementing Executive Order 12549 on debarment and suspension and the Drug-Free Workplace Act of 1988 (41 U.S.C. 701).

(k) 7 CFR part 3052—USDA implementation of OMB Circular No. A–133 regarding audits of institutions of higher education and other nonprofit institutions.

(l) 29 U.S.C. 794, section 504—Rehabilitation Act of 1973, and 7 CFR part 15B (USDA implementation of statute), prohibiting discrimination based upon physical or mental handicap in Federally assisted programs.

§ 1774.9 [Reserved]

Subpart B—Grant Application Processing

§ 1774.10 Applications.

(a) To file an application, an organization must provide their DUNS number. An organization may obtain a DUNS number from Dun and Bradstreet

by calling (1–866–705–5711). To file a complete application, the following information should be submitted:

(1) Standard Form 424, "Application for Federal Assistance (For Non-Construction)."

(2) Standard Form 424A & B, "Budget Information—Non-Construction Programs."

(3) Supporting documentation necessary to make an eligibility determination such as financial statements, audits, organizational documents, or existing debt instruments. The Processing Official will advise applicants regarding the required documents. Applicants that are indebted to RUS will not need to submit documents already on file with the Processing Official as long as such documents are current and valid.

(4) Project narrative detailing the project to be financed with the SEARCH grant funds. The narrative will also provide details on the activities or tasks to be accomplished, objectives, timetables for task completion, and anticipated results.

(5) The applicant's Internal Revenue Service Taxpayer Identification Number (TIN).

(6) Other Forms and certifications. Applicants will be required to submit the following items to the Processing Official, upon notification from the Processing Official to proceed with further development of the full application:

(i) Form RD 442–7, "Operating Budget";

(ii) Form RD 400–1, "Equal Opportunity Agreement";

(iii) Form RD 400–4, "Assurance Agreement";

(iv) Form AD–1047, "Certification Regarding Debarment, Suspension and other Responsibility Matters";

(v) Form AD–1049, Certification regarding Drug-Free Workplace Requirements (Grants) Alternative I For Grantees Other Than Individuals;

(vi) Certifications for Contracts, Grants, and Loans (Regarding Lobbying); and

(vii) Certification regarding prohibited tying arrangements. Applicants that provide electric service must provide the Agency a certification that they will not require users of a water or waste facility financed under this part to accept electric service as a condition of receiving assistance.

(b) Applicants are encouraged to contact the State Office or the Processing Official to find out how to file electronically. The application and supporting documentation must be sent or delivered to the Processing Official, unless it is filed electronically.

§ 1774.11 [Reserved]

§ 1774.12 Eligibility.

The following eligibility requirements must be met:

(a) The applicant must be:

(1) A public body, such as a municipality, county, district, authority, or other political subdivision or a State, territory or commonwealth, or

(2) An organization operated on a not-for-profit basis, such as an association, cooperative, or private corporation. The organization must be an association controlled by a local public body or bodies, or have a broadly based ownership by or membership of people of the local community, or

(3) Indian Tribes on Federal and State reservations and other Federally recognized Indian Tribes.

(b) The area to be served must be financially distressed and rural as defined in § 1774.2 of this part.

§ 1774.13 Limitations.

Grant funds may not be used to:

(a) Fund political or lobbying activities.

(b) Pay for work already completed.

(c) Purchase real estate or vehicles, improve or renovate office space, or repair and maintain privately owned property.

(d) Construct or furnish a building.

(e) Intervene in the Federal regulatory or adjudicatory proceedings.

(f) Sue the Federal Government or any other government entities.

(g) Pay for any other costs that are not allowable under OMB Circular A–87, OMB Circular A–110, OMB Circular A–102 or OMB Circular A–122.

(h) Make contributions or donations to others.

(i) Fund projects that duplicate technical assistance given to implement action plans under the National Forest-Dependent Rural Communities Economic Diversification Act of 1990 (7 U.S.C. 6613). Applicants cannot receive both grants made under this part and grants that the Forest Service makes to implement the action plans for five continuous years from the date of grant approval by the Forest Service.

(j) To pay an outstanding judgment obtained by the United States in a Federal Court (other than in the United States Tax Court), which has been recorded. An applicant will be ineligible to receive a loan or grant until the judgment is paid in full or otherwise satisfied.

§ 1774.14 Eligible grant purposes.

(a) Eligible predevelopment planning costs are feasibility studies, preliminary design assistance, and technical assistance as each is defined in § 1774.2. The eligible predevelopment activities funded with these grant funds must be agreed to and accepted by the Agency prior to the disbursement of the SEARCH grant. The predevelopment planning costs must be related to a proposed project that meets the following requirements:

(1) To construct, enlarge, extend, or otherwise improve rural water, sanitary sewage, solid waste disposal, and storm wastewater disposal facilities.

(2) To construct or relocate public buildings, roads, bridges, fences, or utilities, and to make other public improvements necessary for the successful operation or protection of facilities authorized in paragraph (a)(1) of this section.

(3) To relocate private buildings, roads, bridges, fences, or utilities, and other private improvements necessary for the successful operation or protection of facilities authorized in paragraph (a)(1) of this section.

(b) The Secretary, subject to the limitation in § 1774.4 of this part, may fund up to 100 percent of the eligible grant costs, not to exceed $30,000.

§ 1774.15 Selection Criteria.

Projects will be selected based primarily on the funding priorities in 7 CFR 1780.17. The Program Official discretionary points stated in 7 CFR1780.17 (e) can also include consideration of the following criteria:

(a) Systems with limited resources.

(b) Smallest systems with lowest incomes.

(c) Funds availability.

§ 1774.16 Grant application processing and approval.

(a) Before starting to assemble the full application, the applicant should arrange through the Processing Official an application conference to provide a basis for orderly application assembly. The processing office will explain program requirements, public information requirements and provide guidance on preparation of items necessary for final determination.

(b) The Processing Official will determine if the application is properly assembled. If not, the applicant will be notified within fifteen Federal working days as to what additional submittal items are needed.

(c) The Processing Official and Approval Official will coordinate their reviews to ensure that the applicant is advised about eligibility and anticipated fund availability within 45 days of the receipt of a completed application.

(d) The Processing Official will submit the following to the Approval Official:

(1) "Water and Waste Project Information Summary";

(2) Form RD 442–3, "Balance Sheet" or a financial statement or audit that includes a balance sheet;

(3) Letter of Conditions;

(4) Form RD 1942–46, "Letter of Intent to Meet Conditions";

(5) Form RD 1940–1, "Request for Obligation of Funds";

§ 1774.17 Grant closing and disbursement.

(a) *Grant closing.* RUS Bulletin 1780–12 "Water or Waste System Grant Agreement" will be completed and executed in accordance with the requirements of grant approval. The grant will be considered closed when RUS Bulletin 1780–12 has been properly executed. Processing officials or Approval officials are authorized to sign the grant agreement on behalf of RUS.

(b) *Grant disbursements.* Agency policy is not to disburse grant funds from the Treasury until they are actually needed by the applicant. If an approved grant includes applicant or other contributions, then these funds will be disbursed before the disbursal of any Agency grant funds.

(c) *Payment for project costs.* Project costs will be monitored by the RUS processing office. Invoices will be approved by the borrower and submitted to the Processing Official for concurrence. The review and acceptance of project costs by the Agency does not attest to the correctness of the amounts, the quantities shown or that the work has been performed under the terms of the agreements or contracts.

(d) *Use of remaining funds.* Funds remaining after all costs incident to the basic project have been paid or provided for will not include applicant contributions if SEARCH grants funds are financing less than 100 percent of the project. Funds remaining may be considered in direct proportion to the amounts obtained from each source. Remaining funds will be handled as follows:

(1) Remaining funds may be used for eligible grant purposes as described in 1774.14 of this subpart, or

(2) Grant funds not expended will be canceled. Prior to the actual cancellation, the borrower, its attorney and its engineer will be notified of RUS' intent to cancel the remaining funds.

§ 1774.18 Reporting requirements, accounting methods and audits.

All Agency grantees will follow the reporting requirements as outlined in 7 CFR 1780.47.

§ 1774.19 Applications determined ineligible.

If at any time an application is determined ineligible, the processing office will notify the applicant in writing of the reasons. The notification to the applicant will state that an appeal of this decision may be made by the applicant under 7 CFR part 11.

§ 1774.20 Conflict of Interest.

Any processing or servicing activity conducted pursuant to this part involving authorized assistance to Rural Development employees with Water and Environmental Programs responsibility, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this title. Applicants of this assistance are required to identify any known relationship or association with an RUS employee.

§§ 1774.21–1774.23 [Reserved]

§ 1774.24 Exception authority.

The Administrator may, in individual cases, make an exception to any requirement or provision of this part which is not inconsistent with the authorizing statute or other applicable law and is determined to be in the Government's interest. Requests for exceptions must be made in writing by the State Director and supported with documentation to explain the adverse effect on the Government's interest, propose alternative course(s) of action, and show how the adverse affect will be eliminated or minimized if the exception is granted. The exception decision will be documented in writing, signed by the Administrator, and retained in the files.

§ 1774.25–1774.99 [Reserved]

§ 1774.100 OMB Control Number.

The information collection requirements in this part will not be effective until approved by the Office of Management and Budget (OMB), subject to the submission of a paperwork package to OMB and assigned an OMB Control Number.

Dated: May 10, 2010.

Jonathan Adelstein,

Administrator, Rural Utilities Service.

[FR Doc. 2010–15265 Filed 6–23–10; 8:45 am]

BILLING CODE 3410–15–P

FARM CREDIT ADMINISTRATION

12 CFR Parts 604, 607, 612, 614, 615, 618, and 627

RIN 3052–AC63

Farm Credit Administration Board Meetings; Assessment and Apportionment of Administrative Expenses; Standards of Conduct and Referral of Known or Suspected Criminal Violations; Loan Policies and Operations; Funding and Fiscal Affairs, Loan Policies and Operations, and Funding Operations; General Provisions; and Title IV Conservators, Receivers, and Voluntary Liquidations; Technical Changes

AGENCY: Farm Credit Administration.

ACTION: Direct final rule.

SUMMARY: The Farm Credit Administration (FCA or Agency) amends the current regulations in parts 604, 607, 612, 614, 615, 618, and 627 to eliminate unnecessary, redundant or outdated regulations, to correct cross-reference errors, and to clarify the intent of a regulatory provision. This direct final rule covers issues that are technical in nature.

DATES: If no significant adverse comment is received on or before July 26, 2010, these regulations shall be effective upon the expiration of 30 days after publication in the **Federal Register** during which either or both Houses of Congress are in session. We will publish notice of the effective date in the **Federal Register**. If we receive significant adverse comment on an amendment, paragraph, or section of this rule, and that provision may be addressed separately from the remainder of the rule, we will withdraw that amendment, paragraph, or section and adopt as final those provisions of the rule that are not the subject of a significant comment. In such a case, we would then inform you of how we expect to continue further rulemaking on the provisions that were the subject of significant adverse comment.

FOR FURTHER INFORMATION CONTACT:

Jacqueline R. Melvin, Policy Analyst, Office of Regulatory Policy, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4498, TTY (703) 883–4434, or

Mary Alice Donner, Senior Attorney, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TTY (703) 883–4020.

SUPPLEMENTARY INFORMATION:

I. Objective

The objective of this direct final rule is to carry out the FCA Board's commitment to the principles contained in the Board's Policy Statement on Regulatory Philosophy,[1] which includes the elimination of outdated regulations and technical amendments to ensure that regulations are accurate. In furtherance of this objective, the Agency is making a number of technical changes to its regulations.

II. Section-by-Section Analysis

A. Section 604.420(i)(1)—Farm Credit Administration Board Meetings; § 607.2(j)—Assessment and Apportionment of Administrative Expenses; § 612.2300(a)—Standards of Conduct and Referral of Known or Suspected Criminal Violations; §§ 615.5030(b) and 615.5560—Funding and Fiscal Affairs, Loan Policies and Operations, and Funding Operations; and § 627.2705(b)—Title IV Conservators, Receivers, and Voluntary Liquidations

In each of the above-listed sections, the direct final rule eliminates obsolete references or deletes obsolete regulations that directly or indirectly relate to either the Farm Credit System Assistance Board (Assistance Board) or the Farm Credit System Financial Assistance Corporation (Financial Assistance Corporation or FAC). The Assistance Board's charter was cancelled by the FCA Board, effective December 31, 1992, as required by section 6.12 of the Farm Credit Act of 1971, as amended (Act). In addition, the Financial Assistance Corporation's charter was cancelled by the FCA Board on December 31, 2006.

B. Section 614.4265(d)(Subpart F)—Collateral Evaluation Requirements

The direct final rule amends § 614.4265(d) to correctly reference paragraph (c) of that section regarding the evaluation of the income-earning and debt-servicing capacity for real property.

C. Sections 614.4510, 614.4512, and 614.4513 (Subpart N)—Loan Servicing Requirements; State Agricultural Loan Mediation Programs; Right of First Refusal

We previously removed §§ 614.4514 through 614.4522 of subpart N, part 614, and redesignated them to the newly created part 617 to make the borrower rights rules more readily identifiable; however, we overlooked §§ 614.4510, 614.4512 and 614.4513 in the relocation.[2] Therefore, this direct final rule redesignates the remaining regulations, § 614.4510 and § 614.4513 of subpart N, part 614, to § 614.4170 and § 614.4175 of subpart D, part 614. In addition, the definitions in subpart N, part 614, in § 614.4512 are redundant and are removed.

D. Section 618.8320 (Subpart G)—Releasing Information

The direct final rule amends § 618.8320(b)(4) by inserting the phrase ", administration of credit," after "extension of credit". This is a technical change that does not alter the intended meaning of the provision but clarifies that borrower information that is shared in connection with the extension of credit and the collection of loans would also necessarily include the administration of credit for the confidential use of Farm Credit System (System) institutions.

E. Section 627.2735 (Subpart B)—Notice to Holders of Uninsured Accounts and Stockholders

The direct final rule amends § 627.2735(a) by deleting the reference to § 614.4513 and replacing it with § 614.4175 to conform to the redesignation of that provision described in part C of this preamble.

III. Direct Final Rule

We are amending regulations described in the "Section-by-Section Analysis" above by a direct final rulemaking. The Administrative Conference of the United States recommends direct final rulemaking for Federal agencies to enact noncontroversial regulations on an expedited basis, without the usual notice and comment period.[3] This process enables us to reduce the time and resources we need to develop, review, and publish a final rule while still affording the public an adequate opportunity to comment or object to the rule.

In a direct final rulemaking, we notify the public that the rule will become final on a specified date unless we receive a significant adverse comment during the comment period. A significant adverse comment is one where the commenter explains why the rule would be inappropriate (including challenges to its underlying premise or approach), ineffective, or unacceptable without a change. In general, a significant adverse comment would raise an issue serious enough to warrant a substantive response from the Agency in a notice-and-comment proceeding.

We believe that a direct final rulemaking is the appropriate method for amending the regulations in Section II above because the changes are technical in nature and do not substantively alter the rights or responsibilities of any party. We do not anticipate there will be significant adverse comments. If, however, we receive a significant adverse comment during the comment period, we will publish a notice of withdrawal of the relevant provisions of this rule that will also indicate how further rulemaking will proceed. If we receive no significant adverse comments, we will publish notice of the effective date of the rule following the required Congressional waiting period under section 5.17(c)(1) of the Farm Credit Act of 1971, as amended.

IV. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the FCA hereby certifies that the direct final rule will not have a significant economic impact on a substantial number of small entities. Each of the banks in the System, considered together with its affiliated associations, has assets and annual income in excess of the amounts that would qualify them as small entities. Therefore, System institutions are not "small entities" as defined in the Regulatory Flexibility Act.

List of Subjects in 12 CFR Parts 604, 607, 612, 614, 615, 618, and 627

Accounting, Agriculture, Archives and records, Banks, Banking, Claims, Conflict of interest, Credit, Crime, Foreign trade, Government securities, Insurance, Investigations, Investments, Organization and functions (Government agencies), Reporting and recordkeeping requirements, Rural areas, Sunshine Act, Technical assistance.

■ For the reasons stated in the preamble, parts 604, 607, 612, 614, 615, 618, and 627 of chapter VI, title 12 of the Code of Federal Regulations are amended as follows:

PART 604—FARM CREDIT ADMINISTRATION BOARD MEETINGS

■ 1. The authority citation for part 604 continues to read as follows:

Authority: Secs. 5.9, 5.17 of the Farm Credit Act (12 U.S.C. 2243, 2252).

■ 2. Amend § 604.420 by revising paragraph (i)(1) to read as follows:

[1] *See* 70 FR 71142, November 25, 2005.

[2] *See* 69 FR 10901, March 9, 2004.

[3] Recommendation 95–4, referencing the Administrative Procedure Act "good cause" exemption at 5 U.S.C. 553(b)(B), adopted June 15, 1995.

§ 604.420 Exemptive provisions.

* * * * *

(i) * * *

(1) Significantly endanger the stability of any Farm Credit System institution, including banks, associations, service organizations, or the Funding Corporation; or

* * * * *

PART 607—ASSESSMENT AND APPORTIONMENT OF ADMINISTRATIVE EXPENSES

■ 3. The authority citation for part 607 continues to read as follows:

Authority: Secs. 5.15, 5.17 of the Farm Credit Act (12 U.S.C. 2250, 2252) and 12 U.S.C. 3025.

§ 607.2 [Amended]

■ 4. Amend § 607.2 by removing the words "the Farm Credit System Financial Assistance Corporation," in paragraph (j).

PART 612—STANDARDS OF CONDUCT AND REFERRAL OF KNOWN OR SUSPECTED CRIMINAL VIOLATIONS

■ 5. The authority citation for part 612 continues to read as follows:

Authority: Secs. 5.9, 5.17, 5.19 of the Farm Credit Act (12 U.S.C. 2243, 2252, 2254).

Subpart B—Referral of Known or Suspected Criminal Violations

§ 612.2300 [Amended]

■ 6. Amend § 612.2300 by removing the words "the Farm Credit System Financial Assistance Corporation," in the first sentence of paragraph (a).

PART 614—LOAN POLICIES AND OPERATIONS

■ 7. The authority citation for part 614 continues to read as follows:

Authority: 42 U.S.C. 4012a, 4104a, 4104b, 4106, and 4128; secs. 1.3, 1.5, 1.6, 1.7, 1.9, 1.10, 1.11, 2.0, 2.2, 2.3, 2.4, 2.10, 2.12, 2.13, 2.15, 3.0, 3.1, 3.3, 3.7, 3.8, 3.10, 3.20, 3.28, 4.12, 4.12A, 4.13B, 4.14, 4.14A, 4.14C, 4.14D, 4.14E, 4.18, 4.18A, 4.19, 4.25, 4.26, 4.27, 4.28, 4.36, 4.37, 5.9, 5.10, 5.17, 7.0, 7.2, 7.6, 7.8, 7.12, 7.13, 8.0, 8.5 of the Farm Credit Act (12 U.S.C. 2011, 2013, 2014, 2015, 2017, 2018, 2019, 2071, 2073, 2074, 2075, 2091, 2093, 2094, 2097, 2121, 2122, 2124, 2128, 2129, 2131, 2141, 2149, 2183, 2184, 2201, 2202, 2202a, 2202c, 2202d, 2202e, 2206, 2206a, 2207, 2211, 2212, 2213, 2214, 2219a, 2219b, 2243, 2244, 2252, 2279a, 2279a-2, 2279b, 2279c–1, 2279f, 2279f–1, 2279aa, 2279aa–5); sec. 413 of Pub. L. 100–233, 101 Stat. 1568, 1639.

Subpart F—Collateral Evaluation Requirements

§ 614.4265 [Amended]

■ 8. Section 614.4265(d) is amended by removing the reference to "paragraph (d)" and adding in its place, a reference to "paragraph (c)."

Subpart I—Loss-Sharing Agreements

§ 614.4341 [Removed]

■ 9. Section 614.4341 is removed.

Subpart N—[Removed and Reserved]

§§ 614.4510 and 614.4513 [Redesignated as §§ 614.4170 and 614.4175 of subpart D]

■ 10. Subpart N is amended by redesignating §§ 614.4510 and 614.4513 as newly designated §§ 614.4170 and 614.4175 in subpart D of part 614, removing § 614.4512, and reserving subpart N.

PART 615—FUNDING AND FISCAL AFFAIRS, LOAN POLICIES AND OPERATIONS, AND FUNDING OPERATIONS

■ 11. The authority citation for part 615 continues to read as follows:

Authority: Secs. 1.5, 1.7, 1.10, 1.11, 1.12, 2.2, 2.3, 2.4, 2.5, 2.12, 3.1, 3.7, 3.11, 3.25, 4.3, 4.3A, 4.9, 4.14B, 4.25, 5.9, 5.17, 6.20, 6.26, 8.0, 8.3, 8.4, 8.6, 8.8, 8.10, 8.12 of the Farm Credit Act (12 U.S.C. 2013, 2015, 2018, 2019, 2020, 2073, 2074, 2075, 2076, 2093, 2122, 2128, 2132, 2146, 2154, 2154a, 2160, 2202b, 2211, 2243, 2252, 2278b, 2278b–6, 2279aa, 2279aa–3, 2279aa–4, 2279aa–6, 2279aa–8, 2279aa–10, 2279aa–12); sec. 301(a) of Pub. L. 100–233, 101 Stat. 1568, 1608.

Subpart A—Funding

§ 615.5030 [Amended]

■ 12. Amend § 615.5030 by removing paragraph (b) and the designation for paragraph (a).

Subpart R—[Removed and Reserved]

■ 13. Subpart R, consisting of § 615.5560, is removed and reserved.

PART 618—GENERAL PROVISIONS

■ 14. The authority citation for part 618 continues to read as follows:

Authority: Secs. 1.5, 1.11, 1.12, 2.2, 2.4, 2.5, 2.12, 3.1, 3.7, 4.12, 4.13A, 4.25, 4.29, 5.9, 5.10, 5.17 of the Farm Credit Act (12 U.S.C. 2013, 2019, 2020, 2073, 2075, 2076, 2093, 2122, 2128, 2183, 2200, 2211, 2218, 2243, 2244, and 2252).

Subpart G—Releasing Information

§ 618.8320 [Amended]

■ 15. Amend § 618.8320 by adding the phrase ", administration of credit," after the phrase "extension of credit" in paragraph (b)(4).

PART 627—TITLE IV CONSERVATORS, RECEIVERS, AND VOLUNTARY LIQUIDATIONS

■ 16. The authority citation for part 627 continues to read as follows:

Authority: Secs. 4.2, 5.9, 5.10, 5.17, 5.51, 5.58, 5.61 of the Farm Credit Act (12 U.S.C. 2183, 2243, 2244, 2252, 2277a, 2277a–7, 2277a–10).

Subpart A—General

■ 17. Section 627.2705 is amended by revising paragraph (b) to read as follows:

§ 627.2705 Definitions.

* * * * *

(b) *Farm Credit institution(s)* or *institution(s)* means all associations, banks, service corporations chartered under title IV of the Act, and the Federal Farm Credit Banks Funding Corporation.

* * * * *

Subpart B—Receivers and Receiverships

§ 627.2735 [Amended]

■ 18. Section 627.2735(a) is amended by removing the reference "§ 614.4513" and adding in its place, the reference "§ 614.4175".

Dated: June 18, 2010.

Roland E. Smith,

Secretary, Farm Credit Administration Board.

[FR Doc. 2010–15327 Filed 6–23–10; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2010–0332]

RIN 1625–AA00

Safety Zone; Fireworks Display in Stevenson, WA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The U.S. Coast Guard is establishing a temporary safety zone covering the waters of the Columbia River in the vicinity of Stevenson, Washington. The safety zone is necessary to help ensure the safety of the maritime public during the fireworks display and will do so by prohibiting all persons and vessels from

entering the safety zone unless authorized by the Captain of the Port or his designated representative.

DATES: This rule is effective from 8 p.m. until 11 p.m. on July 4, 2010.

DATES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2010–0332 and are available online by going to *http://www.regulations.gov,* inserting USCG–2010–0332 in the "Keyword" box, and then clicking "Search." They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail MST1 Jaime Sayers, Waterways Management Division, Sector Portland, Coast Guard; telephone 503–240–9319, e-mail *D13–SG–SecPortlandWWM@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is contrary to the public interest to delay the effective date of this rule. Delaying the effective date by first publishing an NPRM would be contrary to the safety zone's intended objective since immediate action is needed to protect person's and vessels against the hazards associated with fireworks displays on navigable waters. Such hazards include premature detonations, dangerous detonations, dangerous projectiles and falling or burning debris. Additionally, the zone should have negligible impact on vessel transits due to the fact that vessels will be limited from the area for only three hours. Accordingly, under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** because due to the need for immediate action, the restriction of vessel traffic is necessary to protect life, property and the environment; therefore, a 30-day notice is impracticable. Delaying the effective date would be contrary to the safety zone's intended objectives of protecting persons and vessels involved in the event, and enhancing public and maritime safety.

Basis and Purpose

Fireworks displays create a hazardous condition for the maritime public because of the large number of vessels that congregate near the displays as well as the noise, falling debris, and explosions that occur during the event. The establishment of a safety zone around the display helps to ensure the safety of the maritime public by prohibiting all persons and vessels from coming too close to the fireworks display and the associated hazards.

Discussion of Rule

The Coast Guard is establishing a temporary safety zone on specified waters of the Columbia River in the vicinity of Stevenson, Washington. Specifically, the safety zone would include all waters within an area whose boundary is defined by connecting the following points: starting from the shore at 45°41′26.70″ N/121°53′36.80″ W; thence continuing to 45°41′24.62″ N/121°53′40.85″ W; thence continuing to 45°41′18.10″ N/121°53′27.86″ W; thence continuing to 45°41′ 25.32″ N/121°53′19.42″ W; thence continuing to 45° 41′30.32″ N/121°53′27.14″ W; thence continuing back to the starting point at 45°41′26.70″ N/121°53′36.80″ W. All persons and vessels will be prohibited from entering the safety zone unless authorized by the Captain of the Port or his designated representative.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. Although this temporary rule restricts access to the safety zone, the effect of the rule will not be significant because: (i) The safety zone will only be in effect for three hours on one day, and (ii) the zone is of a limited size.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities because the zone will be in effect for only be in effect for three hours on one day. This rule may affect the following entities some of which may be small entities: The owners or operators of vessels wishing to transit or anchor in that portion of the Columbia River between 8 p.m. and 11 p.m. on July 4, 2010.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. This rule involves the establishment of a safety zone. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T13–143 to read as follows:

§ 165.T13–143 Safety Zone; Fireworks Display in Stevenson, WA

(a) *Location.* The following area is a safety zone: all waters within an area whose boundary is defined by connecting the following points: starting from the shore at 45°41′26.70″ N/121°53′36.80″ W; thence continuing to 45°41′24.62″ N/121°53′40.85″ W; thence continuing to 45°41′18.10″ N/121°53′27.86″ W; thence continuing to 45°41′25.32″ N/121°53′19.42″ W; thence continuing to 45°41′30.32″ N/121°53′27.14″ W; thence continuing back to the starting point at 45°41′26.70″ N/121°53′36.80″ W.

(b) *Regulations.* In accordance with the general regulations in § 165.23 of this part, no person or vessel may enter or remain in the safety zone created by paragraph (a) of this section without the permission of the Captain of the Port, Sector Portland or his designated representative.

(c) *Enforcement Period.* The safety zone created in paragraph (a) of this section will be in effect from 8 p.m. until 11 p.m. on July 4, 2010.

Dated: May 14, 2010.

F.G. Myer,

Captain, U.S. Coast Guard, Captain of the Port, Portland.

[FR Doc. 2010–15274 Filed 6–23–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2010–0214]

RIN 1625–AA00

Safety Zone; North Jetty, Named the Barview Jetty, Tillamook Bay, OR

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone surrounding the north jetty, named the Barview Jetty near Tillamook Bay, Oregon. The safety zone is necessary to help ensure the safety of work crews and the maritime public while the jetty is being repaired and will do so by prohibiting all persons and vessels from entering or remaining within 250 feet of the jetty unless specifically authorized by the Captain of the Port or his designated representative.

DATES: *Effective Date:* This rule is effective in the CFR from June 24, 2010 until 11:59 p.m. on September 30, 2010. This rule is effective with actual notice for purposes of enforcement beginning 12:01 a.m. on June 15, 2010.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2010–0214 and are available online by going to *http://www.regulations.gov,* inserting USCG–2010–0214 in the "Keyword" box, and then clicking "Search." This material is also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail MST1 Jaime Sayers, Waterways Management Branch, Coast Guard Sector Portland; telephone 503–240–9319, e-mail *Jaime.A.Sayers@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On April 28, 2010, we published a notice of proposed rulemaking (NPRM) entitled "Safety Zone; North Jetty, Named the Barview Jetty, Tillamook Bay, OR" in the **Federal Register** (75 FR 22336). We received one comment on the proposed rule. There were no requests for a public meeting and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register.** Due to the need for immediate action, the restriction of vessel traffic is necessary to protect life, property and the environment; therefore, a 30-day notice is impracticable. Delaying the effective date would be contrary to the safety zone's intended objectives of protecting persons and vessels involved in the event, and enhancing public and maritime safety.

Basis and Purpose

The north jetty, named the Barview Jetty, near Tillamook Bay, Oregon has deteriorated to the point that the United States Army Corps of Engineers has contracted Kiewit Corporation to repair the jetty. The repairs will begin on June 15, 2010 and will involve the use of a track mounted Manitowoc 18,000 lb crane with as much as 200 feet of boom. The crane will be used to move large granite boulders weighing approximately 20 to 50 tons each by lifting them up, circling them out over the waterway on either side of the north jetty, and placing them into the jetty.

Due to the inherent dangers associated with such operations, the safety zone created by this rule is necessary to help ensure the safety of work crews and the maritime public while the jetty is being repaired. It will do so by prohibiting all persons and vessels from entering or remaining in the zone when work is being conducted on the jetty unless specifically authorized by the Captain of the Port or his designated representative.

Discussion of Comments and Changes

The Coast Guard received one comment on this safety zone regarding the ability of surfers to use the "rip adjacent to the jetty to get out to the breaking waves." The Coast Guard agrees the temporary safety zone will restrict access to the area, and we have made a change to the rule in light of this comment by adding language that the safety zone will be enforced when work is being conducted on the jetty, between the hours of 5:30 a.m. and 7:30 p.m. Monday through Saturday, unless otherwise required. The purpose of the safety zone is to protect the public from the dangers associated with the construction project and due to safety concerns the area may be closed to public access by the company working on the jetty. The public will be notified of the enforcement and suspension of enforcement of the safety zone by Broadcast Notice to Mariners in accordance with the procedures outlined in this regulation.

Discussion of Rule

The safety zone created by this rule will cover all waters surrounding the Barview jetty within 250 feet starting at latitude 45°34′12″ N, longitude 123°57′31″ W; thence heading offshore to latitude 45°34′12″ N, longitude 123°57′58″ W; thence across the tip of the jetty to latitude 45°34′17.5″ N, longitude 123°57′58″ W; thence back inland to latitude 45°34′15″ N, longitude 123°57′31″ W. All persons and vessels will be prohibited from entering or remaining in the zone unless specifically authorized by the Captain of the Port or his designated representative.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. Although this regulation restricts access to the safety zone, the effect of the rule will not be significant because: (i) The safety zone will only be in effect during the 3½ months repairs are being made to the north jetty, named the Barview Jetty; (ii) the zone is of limited size; and (iii) maritime traffic will be able to transit the zone with the permission of the Captain of the Port or his designated representative.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule may affect the following entities some of which may be small entities: The owners or operators of vessels wishing to transit the safety zone established by this rule. The rule will not have a significant economic impact on a substantial number of small entities, however, because the safety zone will only be in effect during the 3½ months repairs are being made to the north jetty, named the Barview Jetty, and maritime traffic will be able to transit the zone with the permission of

the Captain of the Port or his designated representative.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), in the NPRM we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g) of the Instruction. This rule involves the establishment of a safety zone. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T13–137 to read as follows:

§ 165.T13–137 Safety Zone; North Jetty, Named the Barview Jetty, Tillamook Bay, OR.

(a) *Location.* The following area is a safety zone: All waters within a 250 feet radius of the north jetty, named the Barview Jetty, near Tillamook Bay, Oregon starting at latitude 45°34′12″ N, longitude 123°57′31″ W; thence heading offshore to latitude 45°34′12″ N, longitude 123°57′58″ W; thence across the tip of the jetty to latitude 45°34′17.5″ N, longitude 123°57′58″ W; thence back inland to latitude 45° 34′ 15″ N, longitude 123°57′31″ W.

(b) *Regulations.* In accordance with the general regulations in § 165.23, no

person may enter or remain in the safety zone created in paragraph (a) of this section or bring, cause to be brought, or allow to remain in the safety zone created in paragraph (a) of this section any vehicle, vessel or object unless authorized by the Captain of the Port or his designated representative.

(c) *Enforcement.* The safety zone will be enforced daily June 15, 2010 through September 31, 2010 between the hours of 5:30 a.m. and 7:30 p.m.

(1) The Captain of the Port, Sector Portland, will notify the public of the enforcement and suspension of enforcement of the safety zone established by this section via any means that will provide as much notice as possible to the public. These means might include some or all of those listed in 33 CFR 165.7(a). The primary method of notification, however, will be through Broadcast Notice to Mariners and local Notice to Mariners.

(d) *Effective Period.* The safety zone created in paragraph (a) of this section will be in effect from 12:01 a.m. June 15, 2010 until 11:59 p.m. September 30, 2010 while work is being conducted on the jetty.

Dated: June 11, 2010.

F.G. Myer,

Captain, U.S. Coast Guard, Captain of the Port, Portland.

[FR Doc. 2010–15273 Filed 6–23–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Parts 2 and 7

[Docket No. PTO–T–2010–0014]

RIN 0651–AC39

Trademark Technical and Conforming Amendments

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Interim final rule with request for comments.

SUMMARY: The United States Patent and Trademark Office ("USPTO") is amending the Rules of Practice in Trademark Cases to implement the Trademark Technical and Conforming Amendment Act of 2010. The rule changes harmonize the framework for submitting trademark registration maintenance filings to the USPTO by permitting holders of international registrations with an extension of protection to the United States under the Madrid Protocol ("Madrid Protocol registrants") to file Affidavits or Declarations of Use or Excusable Nonuse at intervals identical to those for nationally issued registrations. The changes additionally allow all trademark owners to cure deficiencies in their maintenance filings, including when the affidavit or declaration is not filed in the name of the owner of the registration.

DATES: This rule is effective on June 24, 2010. Comments must be received by August 23, 2010 to ensure consideration.

ADDRESSES: The Office prefers that comments be submitted via electronic mail message to *TMFRNotices@uspto.gov.* Written comments may also be submitted by mail to Commissioner for Trademarks, P.O. Box 1451, Alexandria, VA 22313–1451, attention Cynthia Lynch; by hand-delivery to the Trademark Assistance Center, Concourse Level, James Madison Building-East Wing, 600 Dulany Street, Alexandria, Virginia, attention Cynthia Lynch; or by electronic mail message via the Federal eRulemaking Portal. See the Federal eRulemaking Portal Web site (*http://www.regulations.gov*) for additional instructions on providing comments via the Federal eRulemaking Portal. The comments will be available for public inspection on the Office's Web site at *http://www.uspto.gov,* and will also be available at the Trademark Legal Policy Office, Madison East, Fourth Floor, 600 Dulany Street, Alexandria, Virginia.

FOR FURTHER INFORMATION CONTACT: Cynthia C. Lynch, Office of the Deputy Commissioner for Trademark Examination Policy, by telephone at (571) 272–8742.

SUPPLEMENTARY INFORMATION:

Statutory Background

The Trademark Technical and Conforming Amendment Act of 2010 became effective on March 17, 2010. Public Law 111–146, 124 Stat. 66 (2010). In addition to making small technical and conforming corrections in Sections 7, 15, and 21 of the Lanham Act, 15 U.S.C. 1057, 1065, and 1071, the legislation makes other more noteworthy changes to Sections 8 and 71, 15 U.S.C. 1058 and 1141k, regarding filing Affidavits or Declarations of Use or Excusable Nonuse to maintain a registration.

Specifically, the legislation gives Madrid Protocol registrants the benefit of six-month grace periods immediately following the statutory time periods for filing their trademark registration maintenance documents under Section 71, 15 U.S.C. 1141k. Previously, no grace period existed at the end of the six-year period following the date of registration in the U.S., and only a three-month grace period existed following the expiration of each successive 10-year period following registration. The new grace periods match those already provided to all other trademark owners for submitting maintenance filings to the USPTO.

In addition, the legislation allows all trademark owners to cure deficiencies in their post-registration maintenance filings outside of the statutory filing period upon payment of a deficiency surcharge, specifically including when affidavits or declarations are not filed in the name of the owner of the registration. Previously, the statute did not provide Madrid Protocol registrants with the opportunity to correct deficiencies in their maintenance filings and allowed all other trademark owners to correct deficiencies outside of the statutory filing period upon payment of the surcharge, except when an affidavit or declaration was not filed in the name of the owner.

The interim final rule revises 37 CFR parts 2 and 7 to implement the Trademark Technical and Conforming Amendment Act of 2010, as referenced above. It applies to all maintenance filings pending with the USPTO as of March 17, 2010, the effective date of the legislation.

References to "the Act," "the Lanham Act," "the Trademark Act," or "the statute" refer to the Trademark Act of 1946, 15 U.S.C. 1051 *et seq.,* as amended.

Rule Making Considerations

The changes made in this interim final rule constitute interpretative rules or rules of agency practice and procedure and are not subject to the requirement for the publication of prior notice of proposed rule making. *See* The Administrative Procedure Act ("APA"), 5 U.S.C. 553(b)(3)(A). The rule changes relate solely to the procedures for maintaining a Federal trademark registration, and merely implement the Trademark Technical and Conforming Amendment Act of 2010, so that the Rules of Practice in Trademark Cases are consistent with the statutory revisions. Thus, they qualify as interpretative rules or rules of agency practice and procedure under 5 U.S.C. 553(b)(A), and prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553(b)(A) (or any other law). *See Cooper Techs. Co.* v. *Dudas,* 536 F.3d 1330, 1336–37, 87 U.S.P.Q.2d 1705, 1710 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), does not require notice

and comment rule making for " 'interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice.' " (quoting 5 U.S.C. 553(b)(A)), *Bachow Communications Inc.* v. *FCC,* 237 F.3d 683, 690 (DC Cir. 2001) (rules governing an application process are "rules of agency organization, procedure, or practice" and are exempt from the APA's notice and comment requirement); *see also Merck & Co., Inc.* v. *Kessler,* 80 F.3d 1543, 1549–50, 38 USPQ2d 1347, 1351 (Fed. Cir. 1996) (the rules of practice promulgated under the authority of former 35 U.S.C. 6(a) (now in 35 U.S.C. 2(b)(2)) are not substantive rules (to which the notice and comment requirements of the APA apply)), and *Fressola* v. *Manbeck,* 36 USPQ2d 1211, 1215 (D.D.C. 1995) ("[i]t is extremely doubtful whether any of the rules formulated to govern patent or trademark practice are other than 'interpretive rules, general statements of policy, * * * procedure, or practice.' ") (quoting C.W. Ooms, The United States Patent Office and the Administrative Procedure Act, 38 Trademark Rep. 149, 153 (1948)). Accordingly, prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553(b)(A) (or any other law), and thirty-day advance publication is not required pursuant to 5 U.S.C. 553(d) (or any other law).

The establishment of a statutory deficiency surcharge in the amount of $100 for Madrid Protocol registrants, who under the new legislation are now afforded the opportunity to correct a deficiency outside the statutory time period, comes in the context of making the treatment of Madrid Protocol registrants' maintenance filing deficiencies consistent with those of non-Madrid Protocol registrants. The legislative history reflects that, with full awareness of the maintenance filing framework, including the $100 deficiency surcharge already in existence for non-Madrid Protocol registrants, Congress sought to establish that same framework for Madrid Protocol registrants. *See, e.g.,* 156 Cong. Rec. H1080 (daily ed. Mar. 3, 2010) (statement of Rep. Johnson) ("However, due to a technical mistake in the Lanham Act, our trademark laws unintentionally prevent trademark owners who file these affidavits for registering extensions under the Madrid Protocol from having the same rights as other U.S. trademark owners. Compliance with regulations should not reduce the rights of trademark owners. Today, we will harmonize our laws with the Madrid Protocol so that this particular injustice no longer occurs.") and 156 Cong. Rec. H1081 (daily ed. Mar. 3, 2010) (statement of Rep. Coble) ("The main purpose of the bill is to bring provisions for maintaining extensions of protection under Madrid in conformity with provisions for maintaining registrations."). Thus, even the establishment of the $100 deficiency surcharge for Madrid Protocol registrants constitutes an interpretative rule.

In the alternative, in the event these rule changes were deemed to require notice and comment, the USPTO has concluded that it has good cause, under 5 U.S.C. 553(b)(B), to adopt the changes made in this interim final rule without prior notice and opportunity for public comment, as such prior notice and comment procedures would be impracticable, unnecessary, and contrary to the public interest. The amendments made to the Trademark Act by the Trademark Technical and Conforming Amendment Act of 2010 became effective on March 17, 2010, and thus apply to maintenance filings for registrations currently pending before the USPTO. The Rules of Practice in Trademark Cases, however, are currently inconsistent with, and do not reflect the benefits provided by, the new legislation. To delay the conforming rule changes for prior notice and comment, and leave the inconsistency in place, is impracticable. In order to rectify the inconsistency as quickly and efficiently as possible, an interim final rule is issued to eliminate the inconsistency between the statute and the rules, while still affording the public the opportunity to comment on the rule changes.

In addition, delaying the rule changes for prior notice and comment is unnecessary because of the nature of the rule changes. As described above, the rule changes merely track the statutory changes, negating the need to consider public input on the substance of the rule changes prior to a final agency determination.

Finally, delaying the rule changes for prior notice and comment would be contrary to the public interest, as it could delay the implementation of the benefits established by the legislation or lead to public confusion caused by the inconsistency between the statute and the rules. This interim final rule, making conforming rule changes and establishing the amount of the statutory deficiency surcharge for Madrid Protocol registrants who wish to correct a deficiency after the statutory deadline, serves the public interest by quickly and efficiently implementing the new legislation, while still affording the public the opportunity to comment on the rule changes.

The USPTO is interested in the public's input and requests public comments regarding these amendments. Therefore, although the interim final rule is effective upon publication, the USPTO will publish in the **Federal Register** a response to any significant adverse comments received along with modifications to the rule, if any.

Discussion of Specific Rules

The following amendments bring the Rules of Practice in Trademark Cases into conformity with the Trademark Act, as amended by the Trademark Technical and Conforming Amendment Act of 2010.

The Office is amending 37 CFR 2.160(a)(3), 2.161(d)(2), and 2.163(c) to replace the references to "section 8(c)(1) of the Act" with "section 8(a)(3) of the Act."

In addition, the Office is amending 37 CFR 2.160(a)(3) to add the wording "per class" to be consistent with the requirements stated in 37 CFR 2.161(d)(2). Similarly, the Office is amending 37 CFR 2.161(d)(2) to replace "late fee" with "grace period surcharge" to be consistent with the language used in 37 CFR 2.160(a)(3) and 37 CFR 7.37(d)(2).

The Office is amending 37 CFR 2.163(a) to replace "[i]f the owner of the registration filed the affidavit or declaration" with "[i]f the affidavit or declaration is filed." Similarly, the Office is amending 37 CFR 2.164(a) to replace "[i]f the owner of the registration files the affidavit or declaration" with "[i]f the affidavit or declaration is filed." These revisions reflect the amendment to the Act providing that when an affidavit or declaration is not filed in the name of the owner of the registration, it is a correctable deficiency.

The Office is amending 37 CFR 2.163(b) to replace the reference to "section 8(a) or section 8(b) of the Act" with "section 8(a) of the Act."

The Office is amending 37 CFR 2.164(a)(1) to replace the reference to "sections 8(a) and 8(b) of the Act" with "sections 8(a)(1) and 8(a)(2) of the Act," replace the reference to "section 8(a) or section 8(b) of the Act" with "section 8(a)(1) or section 8(a)(2) of the Act," and replace the reference to "the deficiency surcharge required by section 8(c)(2) of the Act" with "the deficiency surcharge required by section 8(c) of the Act."

In addition, the Office is amending 37 CFR 2.164(a)(1) to replace "[i]f the owner timely files the affidavit or declaration" with "[i]f the affidavit or declaration is timely filed." This revision reflects the amendment to the

Act providing that when an affidavit or declaration is not filed in the name of the owner of the registration, it is a correctable deficiency.

The Office is amending 37 CFR 2.164(a)(2) to replace the reference to "grace period provided by section 8(c)(1) of the Act" with "grace period provided by section 8(a)(3) of the Act" and replace the reference to "deficiency surcharge required by section 8(c)(2) of the Act" with "deficiency surcharge required by section 8(c) of the Act."

The Office is amending 37 CFR 2.164(b) to remove "or if it is filed within that period by someone other than the owner," and "These deficiencies cannot be cured." The deletions reflect the amendment to the Act providing that when an affidavit or declaration is not filed in the name of the owner of the registration, it is a correctable deficiency.

The Office is amending the heading for 37 CFR 2.168 to account for the rule's applicability to affidavits or declarations under section 71 of the Act.

The Office is amending 37 CFR 2.168(a) to add "[t]he affidavit or declaration filed under section 15 of the Act may also be used as the affidavit or declaration required by section 71, if the affidavit or declaration meets the requirements of both sections 71 and 15." By allowing Madrid Protocol registrants to combine their filings, the Office is providing them with the same filing options available to all other trademark owners.

The Office is adding 37 CFR 7.6(a)(8) to provide for the deficiency surcharge for Madrid Protocol registrants now provided by the Act. Previously, the Act did not confer authority on the USPTO to allow Madrid Protocol registrants to correct deficiencies in their maintenance filings, but did confer such authority with respect to the maintenance filings of other trademark owners. The amendment of the Act eliminated this disparity, and permits the USPTO to allow the correction of deficiencies in Madrid Protocol registrants' maintenance filings after the statutory period with payment of the deficiency surcharge. This surcharge is provided in order to give Madrid Protocol registrants the same benefit available to all other trademark owners, and the amount is the same as the deficiency surcharge applicable to other trademark owners, provided in 37 CFR 2.6(a)(20).

The Office is amending 37 CFR 7.25(a) to remove the reference to § 2.168 since § 2.168 now applies to registered extensions of protection.

The Office is amending 37 CFR 7.36(b)(2) to account for the new time periods provided by the Act for filing the affidavits or declarations due each successive ten-year period following registration. Previously, Madrid Protocol registrants had a six-month window in which to make such filings. They now have the benefit of a full year to make such filings, not including the grace period. The new time periods match those given to other trademark owners.

The Office is adding 37 CFR 7.36(b)(3) to account for the new grace periods provided by the Act. Previously, for Madrid Protocol registrants, no grace period existed at the end of the six-year period following the date of registration and only a three-month grace period existed following the expiration of each successive ten-year period following registration. Now, Madrid Protocol registrants have the benefit of six-month grace periods immediately following the statutory time periods. The newly enacted grace periods match those given to other trademark owners.

The Office is adding 37 CFR 7.36(c) to be analogous to 37 CFR 2.160(b).

The Office is amending 37 CFR 7.37(d)(2) to replace the reference to "section 71(a)(2)(B) of the Act" with "section 71(a)(3) of the Act."

The Office is amending the heading for 37 CFR 7.39 to account for the ability of Madrid Protocol registrants to correct deficiencies in their maintenance filings as provided by the Act.

The Office is adding introductory text to 37 CFR 7.39 that is analogous to the introductory text for 37 CFR 2.163 and includes text previously in 37 CFR 7.39(a).

The Office is amending 37 CFR 7.39(a) to include text previously in 37 CFR 7.39(b) and to state who must sign an Office action response. This is analogous to 37 CFR 2.163(b) and is consistent with the requirements of 37 CFR 2.193(e)(2).

The Office is amending 37 CFR 7.39(b) to account for the grace period provided by the Act and a Madrid Protocol registrant's option of filing a new affidavit or declaration if time remains in the grace period. This is analogous to 37 CFR 2.163(c) as applied to all other trademark owners.

The Office is adding 37 CFR 7.39(c), (c)(1), and (c)(2) to account for the ability of Madrid Protocol registrants to correct deficiencies in their maintenance filings as provided by the Act. This is analogous to 37 CFR 2.164 as applied to all other trademark owners.

The Office is adding § 7.39(d) to be analogous to § 2.164(b).

Rule Making Requirements

Executive Order 13132: This rule making does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

Executive Order 12866: This rule making has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

Regulatory Flexibility Act: As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 (or any other law), neither a regulatory flexibility analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) is required for this interim final rule. *See* 5 U.S.C. 603. Nevertheless, the Deputy General Counsel for General Law of the United States Patent and Trademark Office certifies to the Chief Counsel for Advocacy of the Small Business Administration that this interim final rule will not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 605(b).

The principal impact of this rule making is to ensure that holders of international registrations are provided with greater flexibility to maintain their marks. Furthermore, this increased flexibility harmonizes the requirements between international registrations and nationally issued registrations. The only fee ($100.00) associated with this rule making is to enable international registrants to receive the benefit of correcting a deficiency in their maintenance filings outside the statutory time period. Of the approximately 126,000 affidavits filed under the national registration process, less than 800 (or less than two-thirds of one percent) paid the $100.00 deficiency surcharge. In 2010, the Office estimates approximately 2,700 affidavits will be filed under the international registration process. Assuming that a similar percentage of international registrants would pay the deficiency surcharge, the Office estimates only a small number of registrants would be subject to the fee. For these reasons, the Office has concluded that this interim final rule will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act: This proposed rule involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collection of information involved in this

proposed rule has been reviewed and previously approved by OMB under control number 0651–0051. The United States Patent and Trademark Office is not resubmitting an information collection request to OMB for its review and approval because the changes in this proposed rule would not affect the information collection requirements associated with the information collection under OMB control number 0651–0051.

Comments are invited on: (1) Whether the collection of information is necessary for proper performance of the functions of the agency; (2) the accuracy of the agency's estimate of the burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information to respondents.

Interested persons are requested to send comments regarding these information collections, including suggestions for reduction of this burden, to: (1) The Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10202, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for the Patent and Trademark Office; and (2) Commissioner for Trademarks, P.O. Box 1451, Alexandria, VA 22313–1451 (Attn: Cynthia Lynch).

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

Unfunded Mandates: The Unfunded Mandates Reform Act, at 2 U.S.C. 1532, requires that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any given year. This rule would have no such effect on State, local, and Tribal governments or the private sector.

Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule, the USPTO will submit a report containing the final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. However, this action is not a major rule as defined by 5 U.S.C. 804(2).

List of Subjects

37 CFR Part 2

Administrative practice and procedure, Trademarks.

37 CFR Part 7

Administrative practice and procedure, Trademarks, International registration.

■ For the reasons stated in the preamble and under the authority contained in 15 U.S.C. 1123 and 35 U.S.C. 2, as amended, the Office is amending parts 2 and 7 of title 37 as follows:

PART 2—RULES OF PRACTICE IN TRADEMARK CASES

■ 1. The authority citation for 37 CFR part 2 continues to read as follows:

Authority: 15 U.S.C. 1123, 35 U.S.C. 2, unless otherwise noted.

■ 2. Revise § 2.160(a)(3) to read as follows:

§ 2.160 Affidavit or declaration of continued use or excusable nonuse required to avoid cancellation of registration.

(a) * * *

(3) The affidavit or declaration may be filed within a grace period of six months after the end of the deadline set forth in paragraphs (a)(1) and (a)(2) of this section, with payment of the grace period surcharge per class required by section 8(a)(3) of the Act and § 2.6.

* * * * *

■ 3. Revise § 2.161(d)(2) to read as follows:

§ 2.161 Requirements for a complete affidavit or declaration of continued use or excusable nonuse.

* * * * *

(d) * * *

(2) If the affidavit or declaration is filed during the grace period under section 8(a)(3) of the Act, include the grace period surcharge per class required by § 2.6;

* * * * *

■ 4. Revise § 2.163 to read as follows:

§ 2.163 Acknowledgment of receipt of affidavit or declaration.

The Office will issue a notice as to whether an affidavit or declaration is acceptable, or the reasons for refusal.

(a) If the affidavit or declaration is filed within the time periods set forth in section 8 of the Act, deficiencies may be corrected if the requirements of § 2.164 are met.

(b) A response to the refusal must be filed within six months of the date of issuance of the Office action, or before the end of the filing period set forth in section 8(a) of the Act, whichever is later. The response must be signed by the owner, someone with legal authority to bind the owner (*e.g.,* a corporate officer or general partner of a partnership), or a practitioner qualified to practice under § 11.14 of this chapter, in accordance with the requirements of § 2.193(e)(2).

(c) If no response is filed within this time period, the registration will be cancelled, unless time remains in the grace period under section 8(a)(3) of the Act. If time remains in the grace period, the owner may file a complete, new affidavit.

■ 5. Revise § 2.164 to read as follows:

§ 2.164 Correcting deficiencies in affidavit or declaration.

(a) If the affidavit or declaration is filed within the time periods set forth in section 8 of the Act, deficiencies may be corrected, as follows:

(1) *Correcting deficiencies in affidavits or declarations timely filed within the periods set forth in sections 8(a)(1) and 8(a)(2) of the Act.* If the affidavit or declaration is timely filed within the relevant filing period set forth in section 8(a)(1) or section 8(a)(2) of the Act, deficiencies may be corrected before the end of this filing period without paying a deficiency surcharge. Deficiencies may be corrected after the end of this filing period with payment of the deficiency surcharge required by section 8(c) of the Act and § 2.6.

(2) *Correcting deficiencies in affidavits or declarations filed during the grace period.* If the affidavit or declaration is filed during the six-month grace period provided by section 8(a)(3) of the Act, deficiencies may be corrected before the expiration of the grace period without paying a deficiency surcharge. Deficiencies may be corrected after the expiration of the grace period with payment of the deficiency surcharge required by section 8(c) of the Act and § 2.6.

(b) If the affidavit or declaration is not filed within the time periods set forth in section 8 of the Act, the registration will be cancelled.

■ 6. In § 2.168, revise the heading and paragraph (a) to read as follows:

§ 2.168 Affidavit or declaration under section 15 combined with affidavit or declaration under sections 8 or 71, or with renewal application.

(a) The affidavit or declaration filed under section 15 of the Act may also be used as the affidavit or declaration required by section 8, if the affidavit or declaration meets the requirements of

both sections 8 and 15. The affidavit or declaration filed under section 15 of the Act may also be used as the affidavit or declaration required by section 71, if the affidavit or declaration meets the requirements of both sections 71 and 15.

* * * * *

PART 7—RULES OF PRACTICE IN FILINGS PURSUANT TO THE PROTOCOL RELATING TO THE MADRID AGREEMENT CONCERNING THE INTERNATIONAL REGISTRATION OF MARKS

■ 7. The authority citation for 37 CFR part 7 continues to read as follows:

Authority: 15 U.S.C. 1123, 35 U.S.C. 2, unless otherwise noted.

■ 8. In § 7.6, add paragraph (a)(8) to read as follows:

§ 7.6 Schedule of U.S. process fees.

(a) * * *

(8) For correcting a deficiency in a section 71 affidavit—$100.00

* * * * *

■ 9. Revise § 7.25(a) to read as follows:

§ 7.25 Sections of part 2 applicable to extension of protection.

(a) Except for §§ 2.22–2.23, 2.130–2.131, 2.160–2.166, 2.173, and 2.181–2.186, all sections in parts 2, 10, and 11 of this chapter shall apply to an extension of protection of an international registration to the United States, including sections related to proceedings before the Trademark Trial and Appeal Board, unless otherwise stated.

* * * * *

■ 10. In § 7.36, revise paragraph (b)(2) and add paragraphs (b)(3) and (c) to read as follows:

§ 7.36 Affidavit or declaration of use in commerce or excusable nonuse required to avoid cancellation of an extension of protection to the United States.

* * * * *

(b) * * *

(2) Within the year before the end of every ten-year period after the date of registration in the United States.

(3) The affidavit or declaration may be filed within a grace period of six months after the end of the deadline set forth in paragraphs (b)(1) and (b)(2) of this section, with payment of the grace period surcharge per class required by section 71(a)(3) of the Act and § 7.6.

(c) For the requirements for the affidavit or declaration, see § 7.37.

■ 11. Revise § 7.37(d)(2) to read as follows:

§ 7.37 Requirements for a complete affidavit or declaration of use in commerce or excusable nonuse.

* * * * *

(d) * * *

(2) If the affidavit or declaration is filed during the grace period under section 71(a)(3) of the Act, include the grace period surcharge per class required by § 7.6;

* * * * *

■ 12. Revise § 7.39 to read as follows:

§ 7.39 Acknowledgment of receipt of and correcting deficiencies in affidavit or declaration of use in commerce or excusable nonuse.

The Office will issue a notice as to whether an affidavit or declaration is acceptable, or the reasons for refusal.

(a) A response to the refusal must be filed within six months of the date of issuance of the Office action, or before the end of the filing period set forth in section 71(a) of the Act, whichever is later. The response must be signed by the holder, someone with legal authority to bind the holder (*e.g.,* a corporate officer or general partner of a partnership), or a practitioner qualified to practice under § 11.14 of this chapter, in accordance with the requirements of § 2.193(e)(2).

(b) If no response is filed within this time period, the extension of protection will be cancelled, unless time remains in the grace period under section 71(a)(3) of the Act. If time remains in the grace period, the holder may file a complete, new affidavit.

(c) If the affidavit or declaration is filed within the time periods set forth in section 71 of the Act, deficiencies may be corrected, as follows:

(1) *Correcting deficiencies in affidavits or declarations timely filed within the periods set forth in sections 71(a)(1) and 71(a)(2) of the Act.* If the affidavit or declaration is timely filed within the relevant filing period set forth in section 71(a)(1) or section 71(a)(2) of the Act, deficiencies may be corrected before the end of this filing period without paying a deficiency surcharge. Deficiencies may be corrected after the end of this filing period with payment of the deficiency surcharge required by section 71(c) of the Act and § 7.6.

(2) *Correcting deficiencies in affidavits or declarations filed during the grace period.* If the affidavit or declaration is filed during the six-month grace period provided by section 71(a)(3) of the Act, deficiencies may be corrected before the expiration of the grace period without paying a deficiency surcharge. Deficiencies may be corrected after the expiration of the grace period with payment of the deficiency surcharge required by section 71(c) of the Act and § 7.6.

(d) If the affidavit or declaration is not filed within the time periods set forth in section 71 of the Act, the registration will be cancelled.

Dated: June 18, 2010.

David J. Kappos,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2010–15305 Filed 6–23–10; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2008–0920; FRL–8824–6]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is promulgating significant new use rules (SNURs) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for 17 chemical substances which were the subject of premanufacture notices (PMNs). Two of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. This action requires persons who intend to manufacture, import, or process any of these 17 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification will provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: This rule is effective on August 23, 2010. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on July 8, 2010.

Written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs must be received on or before July 26, 2010 (see Unit VI. of the **SUPPLEMENTARY INFORMATION**).

For additional information on related reporting requirement dates, see Units I.A., VI., and VII. of the **SUPPLEMENTARY INFORMATION**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2008–0920, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Hand Delivery*: OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2008–0920. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2008–0920. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov*, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Tracey Klosterman, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–2209; e-mail address: *klosterman.tracey@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, process, or use the chemical substances contained in this rule. Potentially affected entities may include, but are not limited to:

• Manufacturers, importers, or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in § 721.5. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28 (the corresponding EPA policy appears at 40 CFR part 707, subpart B). Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule on or after July 26, 2010 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

EPA is promulgating these SNURs using direct final procedures. These SNURs will require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of a chemical substance for any activity designated by these SNURs as a significant new use. Receipt of such notices allows EPA to assess risks that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs. Additional rationale and background to these rules are more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** of April 24, 1990 (55 FR 17376). Consult that preamble for further information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2) (see Unit III.). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. The mechanism for reporting under this requirement is established under § 721.5.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to these SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements codified at 19 CFR 12.118 through 12.127, and 19 CFR 127.28 (the corresponding EPA policy appears at 40 CFR part 707, subpart B). Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemical substances subject to a final SNUR must certify their compliance with the SNUR requirements. In addition, any persons who export or intend to export a chemical substance identified in a final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611 (b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

III. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the 17 chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, and the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to this Rule

EPA is establishing significant new use and recordkeeping requirements for 17 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- CAS number (if assigned for non-confidential chemical identities).
- Basis for the TSCA section 5(e) consent order or, for non-section 5(e) SNURs, the basis for the SNUR (i.e., SNURs without TSCA section 5(e) consent orders).
- Toxicity concerns.
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VIII. for more information).
- CFR citation assigned in the regulatory text section of this rule.

The regulatory text section of this rule specifies the activities designated as significant new uses. Certain new uses, including production volume limits (i.e., limits on manufacture and importation volume) and other uses designated in this rule, may be claimed as CBI. Unit IX. discusses a procedure companies may use to ascertain whether a proposed use constitutes a significant new use.

This rule includes 2 PMN substances that are subject to "risk-based" consent orders under TSCA section 5(e)(1)(A)(ii)(I) where EPA determined that activities associated with the PMN substances may present unreasonable risk to human health or the environment. Those consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The so-called "5(e) SNURs" on these PMN substances are promulgated pursuant to § 721.160, and are based on and consistent with the provisions in the

underlying consent orders. The 5(e) SNURs designate as a "significant new use" the absence of the protective measures required in the corresponding consent orders.

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e) consent order usually requires, among other things, that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health. In addition to the actual NCEL concentration, the comprehensive NCELs provisions in TSCA section 5(e) consent orders, which are modeled after Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs) provisions, include requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. However, no comparable NCEL provisions currently exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will state that persons subject to the SNUR who wish to pursue NCELs as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. EPA expects that persons whose § 721.30 requests to use the NCELs approach for SNURs are approved by EPA will be required to comply with NCELs provisions that are comparable to those contained in the corresponding TSCA section 5(e) consent order for the same chemical substance.

This rule also includes SNURs on 15 PMN substances that are not subject to consent orders under TSCA section 5(e). In these cases, for a variety of reasons, EPA did not find that the use scenario described in the PMN triggered the determinations set forth under TSCA section 5(e). However, EPA does believe that certain changes from the use scenario described in the PMN could result in increased exposures, thereby constituting a "significant new use." These so-called "non-5(e) SNURs" are promulgated pursuant to § 721.170. EPA has determined that every activity designated as a "significant new use" in all non-5(e) SNURs issued under § 721.170 satisfies the two requirements stipulated in § 721.170(c)(2), i.e., these significant new use activities, "(i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified" for the PMN substance.

PMN Number P–02–996

Chemical name: Aliphatic triamine (generic).

CAS number: Not available.

Basis for action: The PMN states that the chemical substance will be used as a monomer for polymers with amide or imide links; a crosslinker for epoxy type coatings, adhesives and sealants; a crosslinker for epoxy type composites; a monomer for urea and urethane urea polymers used in coatings; a chemical intermediate for functional chemicals: amides, imides; a chemical intermediate for functional chemicals: isocyanates, salts; and a chemical intermediate for functional chemicals: cyclic amines, etc. Based on test data on the PMN substance and analogous substances, EPA identified concerns for corrosion of the skin, eyes, mucous membranes and lungs; respiratory tract irritation; immunotoxicity; developmental toxicity; and reproductive toxicity from exposure to the PMN substance. In addition, based on test data on the PMN substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 48 parts per billion (ppb) of the PMN substance in surface waters. For the use described in the PMN, worker inhalation and dermal exposures are not expected and releases to water are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance involving an application method which generates a vapor, mist, or aerosol may cause serious health effects and any use of the substance resulting in release to surface waters may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(3)(i), (b)(3)(ii), and (b)(4)(i).

Recommended testing: EPA has determined that the results of the following testing would help characterize the human health and environmental effects of the PMN substance: Either a 90–day inhalation toxicity test (OCSPP Harmonized Test Guideline 870.3465) in rodents, modified for a 28–day exposure, or a repeated dose inhalation toxicity study (Organization for Co-Operation and Development (OECD) 412 test guideline); a prenatal developmental toxicity study (OCSPP Harmonized Test Guideline 870.3700) via the oral route; a reproduction and fertility study (OCSPP Harmonized Test Guideline 870.3800) via the oral route; an immunotoxicity test (OCSPP Harmonized Test Guideline 870.7800) via the oral route; a fish chronic toxicity test (OCSPP Harmonized Test Guideline 850.1400); and a daphnid chronic toxicity test (OCSPP Harmonized Test Guideline 850.1300). All recommended tests should be performed on the PMN substance neutralized with HCl to a pH of 7.0. Further, a certificate of analysis should be included for the test substance.

CFR citation: 40 CFR 721.10184.

PMN Number P–03–106

Chemical name: 1,2-Propanediol, 3-(diethylamino)-, polymers with 5-isocyanato-1- (isocyanatomethyl)-1,3,3-trimethylcyclohexane, propylene glycol and reduced Me esters of reduced polymd. oxidized tetrafluoroethylene, 2-ethyl-1-hexanol-blocked, acetates (salts).

CAS number: 328389–90–8.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a surface treatment agent. Based on test data on analogous substances, EPA believes this substance could cause lung toxicity to workers if inhaled, via irritation to mucous membranes and cationic binding with membranes. For the use described in the PMN, significant worker dermal or inhalation exposure is not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance involving an application method which generates a vapor, mist, or aerosol may result in serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a 90–day inhalation toxicity study (OCSPP Harmonized Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10185.

PMN Number P–04–132

Chemical name: Ethylhexyl oxetane (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: March 7, 2007.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance

will be as an additive for industrial applications. The order was issued under sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA based on findings that this substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the consent order requires use of dermal personal protective equipment, including gloves demonstrated by testing to be impervious (Polyvinyl Alcohol gloves with a thickness of no less than 31.3 mils or Silvershield/4H sleeves with a thickness of no less than 2.7 mils have been shown to satisfy this requirement for up to 8 hours), requires the establishment of a hazard communication program, and limits uses to those listed in the consent order. The SNUR designates as a "significant new use" the absence of these protective measures.

Toxicity concern: Based on test data on the PMN substance, EPA identified concerns for liver toxicity, thyroid toxicity, and systemic toxicity. Further, based on test data on the PMN substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 20 ppb of the PMN substance in surface waters.

Recommended testing: EPA has determined that the following tests would help characterize the human health and environmental effects of the PMN substance: A 90–day oral toxicity test (OCSPP Harmonized Test Guideline 870.3100) in rodents; a fish early-life stage toxicity test (OCSPP Harmonized Test Guideline 850.1400) with rainbow trout; and a daphnid chronic toxicity test (OCSPP Harmonized Test Guideline 850.1300). The order does not require submission of the aforementioned information at any specified time or production volume. However, the order's restrictions on manufacturing, import, processing, distribution in commerce, use and disposal of the PMN substance will remain in effect until the order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citation: 40 CFR 721.10186.

PMN Number P–05–186

Chemical names: (Chemical A) 4-Morpholinepropanamine, N-(1,3-dimethylbutylidene)-; (Chemical B) Fatty acids, tall-oil, reaction products with 4-methyl-2-pentanone and aliphatic polyamine (generic); (Chemical C) Fatty acids, tall-oil, reaction products with (butoxymethyl) oxirane formaldehyde-phenol polymer glycidyl ether, morpholinepropanamine, propylene glycol diamine and aliphatic polyamine, N-(1,3 -dimethylbutylidene) derivs (generic); and (Chemical D) Formaldehyde, polymer with aliphatic diamine and phenol, reaction products with 4-methyl-2-pentanone (generic).

CAS numbers: (Chemical A) 1003863–30–6; (Chemical B) not available; (Chemical C) not available; and (Chemical D) not available.

Basis for action: The PMN states that the substances will be used as curing agents for epoxy coating systems. Based on test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 10 ppb of the PMN in surface waters. For the uses described in the PMN, releases of the substances are not expected to result in surface waters concentrations that exceed 10 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in surface water concentrations exceeding 10 ppb may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of the following tests would help characterize the environmental effects of the PMN substances: A fish acute toxicity test, freshwater and marine (OCSPP Harmonized Test Guideline 850.1075) using the static method with 24–hour renewal intervals; a fish acute toxicity test mitigated by humic acid (OCSPP Harmonized Test Guideline 850.1085) using the static method with 24–hour renewal intervals; an aquatic invertebrate acute toxicity test, freshwater daphnids (OCSPP Harmonized Test Guideline 850.1010) using the static method with 24–hour renewal intervals; and an algal toxicity test, tiers I and II (OCSPP Harmonized Test Guideline 850.5400) using the static method. For all fish and daphnid testing, the dilution water must have a water hardness of less than 180 mg/L calcium carbonate and a total organic carbon (TOC) level of less than 2.0 mg/L. Further, the stock solution should be adjusted to a pH of 7 at study initiation prior to the introduction of test organisms. Study reports must include chemical names, CAS numbers, and composition of the test substance.

CFR citations: 40 CFR 721.10187 (P–05–186, Chemical A); 40 CFR 721.10188 (P–05–186, Chemical B); 40 CFR 721.10189 (P–05–186, Chemical C); and 40 CFR 721.10190 (P–05–186, Chemical D).

PMN Numbers P–06–262, P–06–263, and P–06–264

Chemical names: (P–06–262) Amides, coco, N-[3-(dibutylamino)propyl]; (P–06–263, Chemical A) Amides, coco, N-[3-(dibutylamino)propyl], acrylates; (P–06–263, Chemical B) 1-Butanaminium, N-(3-aminopropyl)-N-butyl-N-(2-carboxyethyl)-, N-coco acyl derivs., inner salts; and (P–06–264) Dialkylcocoamidoalkylpropionate (generic).

CAS numbers: (P–06–262) 851544–20–2; (P–06–263, Chemical A) 851545–09–0; (P–06–263, Chemical B) 851545–17–0; and (P–06–264) not available.

Basis for action: The consolidated PMN states that the substances will be used as intermediates for hydrate inhibitors for oil and gas wells, production pipelines and flowlines (P–06–262); and hydrate inhibitors for oil and gas wells, production pipelines and flowlines (P–06–263 and P–06–264). Based on test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 20 ppb of the PMN substances in surface waters. For the uses described in the PMNs, these substances will not be released to surface waters. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in release to surface waters may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of the following tests would help characterize the environmental effects of the PMN substance: A fish acute toxicity test, freshwater and marine (OCSPP Harmonized Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OCSPP Harmonized Test Guideline 850.1010); an algal toxicity test, tiers I and II (OCSPP Harmonized Test Guideline 850.5400); a ready biodegradability test (OCSPP Harmonized Test Guideline 835.3110); and an activated sludge sorption isotherm (OCSPP Harmonized Test Guideline 835.1110) would help characterize the environmental effects of the PMN substances. Testing should be performed on P–06–264. Further, a certificate of analysis should be included for the test substances.

CFR citations: 40 CFR 721.10191 (P–06–262); 40 CFR 721.10192 (P–06–263, Chemical A); 40 CFR 721.10193 (P–06–263, Chemical B); and 40 CFR 721.10194 (P–06–264).

PMN Numbers P–06–265, P–06–266, and P–06–267

Chemical names: (P–06–265) Dialkylcornoilamidoalkylamine (generic); (P–06–266, Chemical A) Dialkylcornoilamidoacrylate (generic); (P–06–266, Chemical B) Dialkycornoilamidoalkylbetaine (generic); and (P–06–267) Dialkylcornoilamidopropionate (generic).
CAS numbers: (P–06–265) Not available; (P–06–266, Chemical A) not available; (P–06–266, Chemical B) not available; and (P–06–267) not available.
Basis for action: The consolidated PMN states that the substances will be used as intermediates for hydrate inhibitors for oil and gas wells, production pipelines and flowlines (P–06–265); and hydrate inhibitors for oil and gas wells, production pipelines and flowlines (P–06–266 and P–06–267). Based on test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 20 ppb of the PMN substances in surface waters. For the uses described in the PMNs, these substances will not be released to surface waters. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances resulting in release to surface waters may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).
Recommended testing: EPA has determined that the results of the following tests would help characterize the environmental effects of the PMN substance: A fish acute toxicity test, freshwater and marine (OCSPP Harmonized Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OCSPP Harmonized Test Guideline 850.1010); an algal toxicity test, tiers I and II (OCSPP Harmonized Test Guideline 850.5400); a ready biodegradability test (OCSPP Harmonized Test Guideline 835.3110); and an activated sludge sorption isotherm (OCSPP Harmonized Test Guideline 835.1110) would help characterize the environmental effects of the PMN substances. Testing should be performed on P–06–267. Further, a certificate of analysis should be included for the test substances.
CFR citations: 40 CFR 721.10195 (P–06–265); 40 CFR 721.10196 (P–06–266, Chemical A); 40 CFR 721.10197 (P–06–266, Chemical B); and 40 CFR 721.10198 (P–06–267).

PMN Number P–06–702

Chemical name: Substituted aliphatic amine (generic).
CAS number: Not available.
Effective date of TSCA section 5(e) consent order: May 26, 2009.
Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as a polymer curative. The order was issued under sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA based on findings that this substance may present an unreasonable risk of injury to the environment and human health. To protect against these risks, the consent order requires use of dermal personal protective equipment, including gloves demonstrated by testing to be impervious (Ansell NEOX style 9–912 gloves have been shown to satisfy this requirement for up to 110 minutes), use of respiratory personal protective equipment, including a National Institute of Occupational Safety and Health (NIOSH)-approved respiratory protection with an APF of at least 50 or compliance with a New Chemical Exposure Limit (NCEL) of 0.14 mg/m^3 as an 8–hour time-weighted average, establishment of a hazard communication program, and restricts releases to water. The SNUR designates as a "significant new use" the absence of these protective measures.
Toxicity concern: Based on test data on analogous substances, EPA identified concerns for chronic liver toxicity, acute oral toxicity and corrosion to membranes, dermal toxicity, inhalation toxicity, dermal and eye irritation to workers exposed to the PMN substance. EPA set the NCEL at 0.14 mg/m^3 as an 8–hour time-weighted average. In addition, based on test data on the PMN substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters.
Recommended testing: EPA has determined that the results of the following tests would help characterize the health and environmental effects of the PMN substance: A primary skin irritation test (OECD 404 test guideline); a primary eye irritation test (OECD 405 test guideline); a 28–day repeated dose (OECD 407 test guideline) gavage in rats, a fish early life stage toxicity test (OCSPP Harmonized Test Guideline 850.1400); and a daphnid chronic toxicity test (OCSPP Harmonized Test Guideline 850.1300). The PMN submitter has agreed not to exceed the production volume limit without performing the primary skin irritation test (OECD 404 test guideline); primary eye irritation test (OECD 405 test guideline); and 28–day repeated dose test (OECD 407 test guideline) gavage in rats. The order does not require submission of the fish early life-stage toxicity test and the daphnid chronic toxicity test at any specified time or production volume. However, the order's restrictions on manufacturing, import, processing, distribution in commerce, use and disposal of the PMN substance will remain in effect until the order is modified or revoked by EPA based on submission of that or other relevant information.
CFR citation: 40 CFR 721.10199.

PMN Number P–09–75

Chemical name: Benzenacetonitrile, cyclohexylidene-alkyl substituted (generic).
CAS number: Not available.
Basis for action: The PMN states that the generic (non-confidential) use of the PMN substance will be as a component of odorant compositions for highly-dispersive applications. Based on test data on the PMN substance, EPA predicts chronic toxicity to aquatic organisms at concentrations that exceed 123 ppb of the PMN substance in surface waters. For the processing and use scenario and production volume in the amended PMN, releases of the substance are not expected to result in surface water concentrations that exceed 123 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations that exceed 123 ppb, or exceedance of the annual maximum manufacturing and importation limit of 10,000 kg, may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(I).
Recommended testing: EPA has determined that the results of the following tests would help characterize the environmental effects of the PMN substance: A fish early life stage toxicity test (OCSPP Harmonized Test Guideline 850.1400) and a field testing for aquatic organisms test (OCSPP Harmonized Test Guideline 850.1950). The fish early-life stage test should be performed using the flow-through method with measured concentrations. Further, a certificate of analysis should be provided for the test substance. EPA recommends conducting the early life stage fish test first, as the results of this test may affect the choice of species for subsequent field testing.
CFR citation: 40 CFR 721.10200.

V. Rationale and Objectives of the Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are the subjects of these SNURs, EPA

concluded that for 2 of the 17 chemical substances, regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent orders. These SNURs are promulgated pursuant to § 721.160.

In the other 15 cases, where the uses are not regulated under a TSCA section 5(e) consent order, EPA determined that one or more of the criteria of concern established at § 721.170 were met, as discussed in Unit IV.

B. Objectives

EPA is issuing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this rule:

- EPA will receive notice of any person's intent to manufacture, import, or process a listed chemical substance for the described significant new use before that activity begins.
- EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing a listed chemical substance for the described significant new use.
- EPA will be able to regulate prospective manufacturers, importers, or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.
- EPA will ensure that all manufacturers, importers, and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Inventory. Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at *http://www.epa.gov/opptintr/newchems/pubs/invntory.htm*.

VI. Direct Final Procedures

EPA is issuing these SNURs as a direct final rule, as described in § 721.160(c)(3) and § 721.170(d)(4). In accordance with § 721.160(c)(3)(ii) and § 721.170(d)(4)(i)(B), the effective date of this rule is August 23, 2010 without further notice, unless EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments before July 26, 2010.

If EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs before July 26, 2010, EPA will withdraw the relevant sections of this direct final rule before its effective date. EPA will then issue a proposed SNUR for the chemical substance(s) on which adverse or critical comments were received, providing a 30–day period for public comment.

This rule establishes SNURs for a number of chemical substances. Any person who submits adverse or critical comments, or notice of intent to submit adverse or critical comments, must identify the chemical substance and the new use to which it applies. EPA will not withdraw a SNUR for a chemical substance not identified in the comment.

VII. Applicability of Rule to Uses Occurring Before Effective Date of the Rule

Significant new use designations for a chemical substance are legally established as of the date of publication of this direct final rule June 24, 2010.

To establish a significant "new" use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. TSCA section 5(e) consent orders have been issued for 2 chemical substances and the PMN submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which EPA is designating as significant new uses. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no other person may commence such activities without first submitting a PMN. For chemical substances for which an NOC has not been submitted at this time, EPA concludes that the uses are not ongoing. However, EPA recognizes that prior to the effective date of the rule, when chemical substances identified in this SNUR are added to the TSCA Inventory, other persons may engage in a significant new use as defined in this rule before the effective date of the rule. However, 12 of the 17 chemical substances contained in this rule have CBI chemical identities, and since EPA has received a limited number of post-PMN *bona fide* submissions (per §§ 720.25 and 721.11), the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

As discussed in the **Federal Register** of April 24, 1990, EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of this direct final rule rather than as of the effective date of the rule. If uses begun after publication were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements because a person could defeat the SNUR by initiating the significant new use before the rule became effective, and then argue that the use was ongoing before the effective date of the rule. Thus, persons who begin commercial manufacture, import, or processing of the chemical substances regulated through this SNUR will have to cease any such activity before the effective date of this rule. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires (see Unit III.).

EPA has promulgated provisions to allow persons to comply with this SNUR before the effective date. If a person meets the conditions of advance compliance under § 721.45(h), the person is considered exempt from the requirements of the SNUR.

VIII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN, except where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)). Persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see § 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. lists those tests. Unit IV. also lists recommended testing for non-5(e) SNURs. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the Harmonized Test Guidelines referenced in this document electronically, please go to

http://www.epa.gov/ocspp and select "Test Methods and Guidelines." The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at *http://www.oecdbookshop.org* or SourceOECD at *http://www.sourceoecd.org*.

In the TSCA section 5(e) consent orders for several of the chemical substances regulated under this rule, EPA has established production volume limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Under recent TSCA section 5(e) consent orders, each PMN submitter is required to submit each study at least 14 weeks (earlier TSCA section 5(e) consent orders required submissions at least 12 weeks) before reaching the specified production limit. Listings of the tests specified in the TSCA section 5(e) consent orders are included in Unit IV. The SNURs contain the same production volume limits as the TSCA section 5(e) consent orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture, import, or processing.

The recommended tests may not be the only means of addressing the potential risks of the chemical substance. However, SNUN submitting for significant new use without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

IX. Procedural Determinations

By this rule, EPA is establishing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI. This rule cross-references § 721.1725(b)(1) and is similar to that in § 721.11 for situations where the chemical identity of the chemical substance subject to a SNUR is CBI. This procedure is cross-referenced in each SNUR that includes specific significant new uses that are CBI.

Under these procedures a manufacturer, importer, or processor may request EPA to determine whether a proposed use would be a significant new use under the rule. The manufacturer, importer, or processor must show that it has a *bona fide* intent to manufacture, import, or process the chemical substance and must identify the specific use for which it intends to manufacture, import, or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture, import, or process the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers, importers, and processors can combine the *bona fide* submission under the procedure in § 721.1725(b)(1) with that under § 721.11 into a single step.

If EPA determines that the use identified in the *bona fide* submission would not be a significant new use, i.e., the use does not meet the criteria specified in the rule for a significant new use, that person can manufacture, import, or process the chemical substance so long as the significant new use trigger is not met. In the case of a production volume trigger, this means that the aggregate annual production volume does not exceed that identified in the *bona fide* submission to EPA. Because of confidentiality concerns, EPA does not typically disclose the actual production volume that constitutes the use trigger. Thus, if the person later intends to exceed that volume, a new *bona fide* submission would be necessary to determine whether that higher volume would be a significant new use.

X. SNUN Submissions

As stated in Unit II.C., according to § 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in § 720.50. SNUNs must be submitted to EPA, on EPA Form No. 7710–25 in accordance with the procedures set forth in §§ 721.25 and 720.40. This form is available from the Environmental Assistance Division (7408M), 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. Forms and information are also available electronically at *http://www.epa.gov/opptintr/newchems*.

XI. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers, importers, and processors of the chemical substances subject to this rule. EPA's complete economic analysis is available in the docket.

XII. Statutory and Executive Order Reviews

A. Executive Order 12866

This rule establishes SNURs for several new chemical substances that were the subject of PMNs, or TSCA section 5(e) consent orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This

Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070–0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of these SNURs will not have a significant adverse economic impact on a substantial number of small entities. The rationale supporting this conclusion is discussed in this unit. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a "significant new use." Because these uses are "new," based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of over 1,400 SNURs, the Agency receives on average only 5 notices per year. Of those SNUNs submitted from 2006–2008, only one appears to be from a small entity. In addition, the estimated reporting cost for submission of a SNUN (see Unit XI.) is minimal regardless of the size of the firm. Therefore, EPA believes that the potential economic impacts of complying with these SNURs are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this rule. As such, EPA has determined that this rule does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any affect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

E. Executive Order 13132

This action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This rule does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This does not significantly or uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), do not apply to this rule.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This action is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

In addition, since this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

XIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: June 17, 2010.

Wendy C. Hamnett,

Director, Office of Pollution Prevention and Toxics.

■ Therefore, 40 CFR parts 9 and 721 are amended as follows:

PART 9—[AMENDED]

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

■ 2. The table in § 9.1 is amended by adding the following sections in numerical order under the undesignated center heading "Significant New Uses of Chemical Substances" to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * *	* *
.	
Significant New Uses of Chemical Substances	
* * *	* *
721.10184	2070–0012
721.10185	2070–0012
721.10186	2070–0012
721.10187	2070–0012
721.10188	2070–0012
721.10189	2070–0012
721.10190	2070–0012
721.10191	2070–0012
721.10192	2070–0012
721.10193	2070–0012
721.10194	2070–0012
721.10195	2070–0012
721.10196	2070–0012
721.10197	2070–0012
721.10198	2070–0012
721.10199	2070–0012
721.10200	2070–0012
* * *	* *

* * * * *

PART 721—[AMENDED]

■ 3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 4. Add § 721.10184 to subpart E to read as follows:

§ 721.10184 Aliphatic triamine (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as aliphatic triamine (PMN P–02–996) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(y)(1).

(ii) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 5. Add § 721.10185 to subpart E to read as follows:

§ 721.10185 1,2-Propanediol, 3-(diethylamino)-, polymers with 5-isocyanato-1- (isocyanatomethyl)-1,3,3-trimethylcyclohexane, propylene glycol and reduced Me esters of reduced polymd. oxidized tetrafluoroethylene, 2-ethyl-1-hexanol-blocked, acetates (salts).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1,2-propanediol, 3-(diethylamino)-, polymers with 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane, propylene glycol and reduced Me esters of reduced polymd. oxidized tetrafluoroethylene, 2-ethyl-1-hexanol-blocked, acetates (salts) (PMN P–03–106; CAS No. 328389–90–8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(y)(l).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 6. Add § 721.10186 to subpart E to read as follows:

§ 721.10186 Ethylhexyl oxetane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as ethylhexyl oxetane (PMN P–04–132) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(iii), (a)(3)(i), (b) (concentration set at 1.0 percent), and (c). Polyvinyl Alcohol gloves with a thickness of no less than 31.3 mils or Silvershield/4H sleeves with a thickness of no less than 2.7 mils have been shown to satisfy the requirements of § 721.63(a)(3)(i) for up to 8 hours.

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (c), (d), (e) (concentration set at 1.0 percent), (f), (g)(1)(iii), (g)(1)(iv), (g)(2)(i), (g)(2)(v), (g)(3)(ii), and (g)(5).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (f), (g), (h), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

■ 7. Add § 721.10187 to subpart E to read as follows:

§ 721.10187 4-Morpholinepropanamine, N-(1,3-dimethylbutylidene)-.

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified as 4-morpholinepropanamine, N-(1,3-dimethylbutylidene)- (PMN P–05–186, Chemical A; CAS No. 1003863–30–6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=10). However, when this chemical substance is released in combination with any of the substances in § 721.10188, § 721.10189, or § 721.10190, then the value of N shall instead be adjusted according to the following formula:

[(N1 x Release1) + (N2 x Release2) + (N3 x Release3) + (N4 x Release4)] / (Release1 + Release2 + Release3 + Release4) = Adjusted N

Where the "N" variables are the N values for each of the four substances as specified in this section and § 721.10188, § 721.10189, § 721.10190 and the "Release" variables are the number of kilograms released of the respective four substances (in units of kg/site/day) per § 721.91(a).

(ii) [Reserved]

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

■ 8. Add § 721.10188 to subpart E to read as follows:

§ 721.10188 Fatty acids, tall-oil, reaction products with 4-methyl-2-pentanone and aliphatic polyamine (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as fatty acids, tall-oil, reaction products with 4-methyl-2-pentanone and aliphatic polyamine (PMN P–05–186, Chemical B) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=10). However, when this chemical substance is released in combination with any of the substances in § 721.10187, § 721.10189, or § 721.10190, then the value of N shall instead be adjusted according to the following formula:

[(N1 x Release1) + (N2 x Release2) + (N3 x Release3) + (N4 x Release4)] / (Release1 + Release2 + Release3 + Release4) = Adjusted N

Where the "N" variables are the N values for each of the four substances as specified in this section and § 721.10187, § 721.10189, § 721.10190 and the "Release" variables are the number of kilograms released of the respective four substances (in units of kg/site/day) per § 721.91(a).

(ii) [Reserved]

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

■ 9. Add § 721.10189 to subpart E to read as follows:

§ 721.10189 Fatty acids, tall-oil, reaction products with (butoxymethyl) oxirane formaldehyde-phenol polymer glycidyl ether, morpholinepropanamine, propylene glycol diamine and aliphatic polyamine, N-(1,3 -dimethylbutylidene) derivs (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as fatty acids, tall-oil, reaction products with (butoxymethyl) oxirane formaldehyde-phenol polymer glycidyl ether, morpholinepropanamine, propylene glycol diamine and aliphatic polyamine, N-(1,3 -dimethylbutylidene) derivs (PMN P–05–186, Chemical C) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=10). However, when this chemical substance is released in combination with any of the substances in § 721.10187, § 721.10188, or § 721.10190, then the value of N shall instead be adjusted according to the following formula:

[(N1 x Release1) + (N2 x Release2) + (N3 x Release3) + (N4 x Release4)] / (Release1 + Release2 + Release3 + Release4) = Adjusted N

Where the "N" variables are the N values for each of the four substances as specified in this section and § 721.10187, § 721.10188, § 721.10190 and the "Release" variables are the number of kilograms released of the respective four substances (in units of kg/site/day) per § 721.91(a).

(ii) [Reserved]

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

■ 10. Add § 721.10190 to subpart E to read as follows:

§ 721.10190 Formaldehyde, polymer with aliphatic diamine and phenol, reaction products with 4-methyl-2-pentanone (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as formaldehyde, polymer with aliphatic diamine and phenol, reaction products with 4-methyl-2-pentanone (PMN P–05–186; Chemical D) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=10). However, when this chemical substance is released in combination with any of the substances in § 721.10187, § 721.10188, or § 721.10189, then the value of N shall instead be adjusted according to the following formula:

[(N1 x Release1) + (N2 x Release2) + (N3 x Release3) + (N4 x Release4)] / (Release1 + Release2 + Release3 + Release4) = Adjusted N

Where the "N" variables are the N values for each of the four substances as specified in this section and § 721.10187, § 721.10188, § 721.10189 and the "Release" variables are the number of kilograms released of the respective four substances (in units of kg/site/day) per § 721.91(a).

(ii) [Reserved]

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

■ 11. Add § 721.10191 to subpart E to read as follows:

§ 721.10191 Amides, coco, N-[3-(dibutylamino)propyl].

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as amides, coco, N-[3-(dibutylamino)propyl] (PMN P–06–262; CAS No. 851544–20–2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 12. Add § 721.10192 to subpart E to read as follows[U1]:

§ 721.10192 Amides, coco, N-[3-(dibutylamino)propyl], acrylates.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as amides, coco, N-[3-(dibutylamino)propyl], acrylates (PMN P–06–263, Chemical A; CAS No. 851545–09–0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 13. Add § 721.10193 to subpart E to read as follows:

§ 721.10193 1-Butanaminium, N-(3-aminopropyl)-N-butyl-N-(2-carboxyethyl)-, N-coco acyl derivs., inner salts.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1-butanaminium, N-(3-aminopropyl)-N-butyl-N-(2-carboxyethyl)-, N-coco acyl derivs., inner salts (PMN P–06–263, Chemical B; CAS No. 851545–17–0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 14. Add § 721.10194 to subpart E to read as follows:

§ 721.10194 Dialkylcocoamidoalkylpropionate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as dialkylcocoamidoalkylpropionate (PMN P–06–264) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 15. Add § 721.10195 to subpart E to read as follows:

§ 721.10195 Dialkylcornoilamidoalkylamine (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as dialkylcornoilamidoalkylamine (PMN P–06–265) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 16. Add § 721.10196 to subpart E to read as follows:

§ 721.10196 Dialkylcornoilamidoacrylate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as dialkylcornoilamidoacrylate (PMN P–06–266, Chemical A) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 17. Add § 721.10197 to subpart E to read as follows:

§ 721.10197 Dialkycornoilamidoalkylbetaine (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as dialkycornoilamidoalkylbetaine (PMN P–06–266, Chemical B) is subject to reporting under this section for the

significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water*. Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(ii) [Reserved]

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

■ 18. Add § 721.10198 to subpart E to read as follows:

§ 721.10198 Dialkylcornoilamidopropionate (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as dialkylcornoilamidopropionate (PMN P–06–267) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water*. Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(ii) [Reserved]

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

■ 19. Add § 721.10199 to subpart E to read as follows:

§ 721.10199 Substituted aliphatic amine (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as substituted aliphatic amine (PMN P–06–702) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63 (a)(1), (a)(2), (a)(3)(i), (a)(4), (a)(5), (a)(6), (b) (concentration set at 1.0 percent), and (c). Ansell NEOX style 9–912 gloves have been shown to satisfy the requirements of § 721.63(a)(3)(i) for up to 110 minutes. Respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50. The following NIOSH-approved respirators meet the requirements for § 721.63(a)(4): Air purifying, tight-fitting full-face respirator equipped with the appropriate combination cartridges, cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridge) and should include a particulate filter (N100 if oil aerosols are absent, R100, or P100); powered air-purifying respirator equipped with a tight-fitting facepiece (full-face) and the appropriate combination cartridges, cartridges should be tested and approved for the gas/vapor substance (i.e., organic vapor, acid gas, or substance-specific cartridges) and should include High Efficiency Particulate Air (HEPA) filters; supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting face piece (full-face). As an alternative to the respiratory requirements listed here, a manufacturer, importer, or processor may choose to follow the new chemical exposure limit (NCEL) provisions listed in the Toxic Substances Control Act (TSCA) section 5(e) consent order for this substance. The NCEL is 0.14 mg/m^3 as an 8–hour time-weighted average. Persons who wish to pursue NCELs as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will receive NCELs provisions comparable to those contained in the corresponding section 5(e) consent order.

(ii) *Hazard communication program*. Requirements as specified in § 721.72 (a), (b), (c), (d), (e) (concentration set at 1.0 percent), (f), (g)(1)(i), (g)(1)(ii), (g)(1)(iv), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(2)(iv), (g)(2)(v), (g)(3)(i), (g)(3)(ii), (g)(4)(iii), and (g)(5).

(iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(r).

(iv) *Release to water*. Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (f), (g), (h), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section*. The provisions of § 721.1725(b)(1) apply to this section.

■ 20. Add § 721.10200 to subpart E to read as follows:

§ 721.10200 Benzenacetonitrile, cyclohexylidene-alkyl substituted (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as benzenacetonitrile, cyclohexylidene-alkyl substituted (PMN P–09–75) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(s) (10,000 kg).

(ii) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=123).

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

[FR Doc. 2010–15334 Filed 6–23–10; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 27

[WT Docket No. 03–66; RM–10586; FCC 10–107]

Facilitating the Provision of Fixed and Mobile Broadband Access, Educational and Other Advanced Services in the 2150–2162 and 2500–2690 MHz Bands

AGENCY: Federal Communications Commission.

ACTION: Correction.

SUMMARY: The FCC published a document in the **Federal Register** of June 15, 2010, (75 FR 33729), clarifying the requirements necessary for Broadband Radio Service (BRS) and Educational Broadband Service (EBS) licensees to demonstrate substantial service and ensure that BRS licensees of new initial licenses are given a reasonable period of time to deploy service, while ensuring that spectrum is rapidly placed in use. The document contained an incorrect page number in reference to the BRS/EBS Third Further Notice of Proposed Rulemaking citation.

DATES: Effective July 15, 2010.

FOR FURTHER INFORMATION CONTACT: Nancy M. Zaczek, Wireless Telecommunications Bureau, Broadband Division, Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554, at (202) 418–0274 or via the Internet to *Nancy.Zaczek@fcc.gov*.

Correction

In the **Federal Register** 75 FR 33729 published on Tuesday, June 15, 2010, the following correction is made: On page 33730, second column, paragraph 3, first sentence, remove the phrase "74 FR 49335" and insert "74 FR 49356."

Marlene H. Dortch,

Secretary, Federal Communications Commission.

[FR Doc. 2010–15348 Filed 6–23–10; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R1-ES-2009-0036]
[MO 92210-0-0008]

RIN 1018-AV47

Endangered and Threatened Wildlife and Plants; Listing the Flying Earwig Hawaiian Damselfly and Pacific Hawaiian Damselfly As Endangered Throughout Their Ranges

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), determine endangered status under the Endangered Species Act of 1973, as amended (Act), for two species of Hawaiian damselflies, the flying earwig Hawaiian damselfly (*Megalagrion nesiotes*) on the island of Maui and the Pacific Hawaiian damselfly *(M. pacificum*) on the islands of Hawaii, Maui, and Molokai. This final rule implements the Federal protections provided by the Act for these species. We also determine that critical habitat for these two Hawaiian damselflies is prudent, but not determinable at this time.

DATES: This rule becomes effective July 26, 2010.

ADDRESSES: This final rule is available on the Internet at *http://www.regulations.gov* and *http://www.fws.gov/pacificislands*. Comments and materials received, as well as supporting documentation used in the preparation of this rule, will be available for public inspection, by appointment, during normal business hours at: U.S. Fish and Wildlife Service, Pacific Islands Fish and Wildlife Office, 300 Ala Moana Boulevard, Room 3-122, Box 50088, Honolulu, HI 96850; telephone, 808-792-9400; facsimile, 808-792-9581.

FOR FURTHER INFORMATION CONTACT: Loyal Mehrhoff, Field Supervisor, Pacific Islands Fish and Wildlife Office (see **ADDRESSES**). If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800-877-8339.

SUPPLEMENTARY INFORMATION:

Background

Damselflies are insects in the order Odonata, and are close relatives of dragonflies, which they resemble in appearance. Damselflies, however, are slender-bodied and fold their wings parallel to the body while at rest, which readily distinguishes them from their dragonfly relatives, which hold their wings out perpendicular to the body while not in flight.

The flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly are unique, endemic insects found only in the Hawaiian Islands. Historically found on the islands of Hawaii and Maui, the flying earwig Hawaiian damselfly has not been seen on the island of Hawaii for over 80 years. Currently, the species is known only from one location on Maui. The Pacific Hawaiian damselfly was historically found on all of the main Hawaiian Islands except Kahoolawe and Niihau. Currently, the Pacific Hawaiian damselfly is known only from the islands of Hawaii, Maui and Molokai.

The Hawaiian Islands are well known for several spectacular evolutionary radiations (the rapid evolution of new species from a single ancestral type, as a result of adaptation and divergence in response to new ecological conditions) resulting in unique insect fauna found nowhere else in the world. One such group, which began its evolution perhaps as long as 10 million years ago (Jordan *et al*. 2003, p. 89), is the narrow-winged Hawaiian damselfly genus *Megalagrion*. This genus appears to be most closely related to species of *Pseudagrion* elsewhere in the Indo-Pacific (Zimmerman 1948a, pp. 341, 345). The *Megalagrion* species of the Hawaiian Islands have evolved to occupy as many larval breeding niches (different adaptations and ecological conditions for breeding and development of larvae, including chemical, physical, spatial, and temporal factors) as all the rest of the world's damselfly species combined, and in terms of the number of insular-endemic (native to only one island) species, are exceeded only by the radiation of damselfly species of Fiji in the Pacific (Jordan *et al*. 2003, p. 91).

Native Hawaiians apparently did not differentiate the various species, but referred to the native damselflies (and dragonflies) collectively as "pinao," and to the red-colored damselflies specifically as "pinao ula." There has been no traditional European use of a common name for species in the genus *Megalagrion*. In his 1994 taxonomic review of the candidate species of insects of the Hawaiian Islands, Nishida (1994, pp. 4-7) proposed the name "Hawaiian damselflies" as the common name for species in the genus *Megalagrion*. Because this name reflects the restricted distribution of these insects and is nontechnical, the common name "Hawaiian damselflies" is adopted for general use here, and we use the common names flying earwig Hawaiian damselfly and Pacific Hawaiian damselfly to identify the two species addressed in this final rule.

The general biology of Hawaiian damselflies is typical of other narrow-winged damselflies (Polhemus and Asquith 1996, pp. 2-7). The males of most species are territorial, guarding areas of habitat where females lay eggs (Moore 1983a, p. 89). During copulation, and often while the female lays eggs, the male grasps the female behind the head with terminal abdominal appendages to guard the female against rival males; thus males and females are frequently seen flying in tandem.

Female damselflies lay eggs in submerged aquatic vegetation or in mats of moss or algae on submerged rocks, and hatching occurs in about 10 days (Williams 1936, pp. 303, 306, 318; Evenhuis *et al*. 1995, p. 18). In most species of Hawaiian damselflies, the immature larval stages (naiads) are aquatic, breathing through three flattened abdominal gills, and are predaceous, feeding on small aquatic

invertebrates or fish (Williams 1936, p. 303). Naiads may take up to 4 months to mature (Williams 1936, p. 309), after which they crawl out of the water onto rocks or vegetation to molt into winged adults, typically remaining close to the aquatic habitat from which they emerged. The Pacific Hawaiian damselfly exhibits this typical aquatic life history.

In contrast, the naiads of a few species of Hawaiian damselflies are terrestrial or semiterrestrial, living on wet rock faces or in damp terrestrial conditions, inhabiting wet leaf litter or moist leaf axils (the angled juncture of the leaf and stem) of native plants up to several feet above ground (Zimmerman 1970, p. 33; Simon *et al.* 1984, p. 13; Polhemus and Asquith 1996, p. 17). The naiads of these terrestrial and semiterrestrial species have evolved short, thick, hairy gills and in many species are unable to swim (Polhemus and Asquith 1996, p. 75). The flying earwig Hawaiian damselfly is believed to exhibit this terrestrial or semiterrestrial naiad life history.

The Hawaiian damselflies are represented by 23 species and 5 subspecies, and are currently found on 6 of the Hawaiian Islands (Kauai, Oahu, Molokai, Maui, Lanai, and Hawaii). There are more species of *Megalagrion* on the geologically older islands (12 species on Kauai) than on the geologically youngest island (8 species on Hawaii), and there are more single-island endemic species on the older islands (10 on Kauai) than on the youngest island (none on Hawaii) (Jordan *et al.* 2003, p. 91). Historically, *Megalagrion* damselflies were among the most common and conspicuous native Hawaiian insects. Some species commonly inhabited water gardens in residential areas, artificial reservoirs, and watercress farms, and were even abundant in the city of Honolulu, as noted by early collectors of this group (Perkins 1899, p. 76; Perkins 1913, p. clxxviii; Williams 1936, p. 304).

Beginning with the extensive stream and wetland conversion, alteration, and modification, and degradation of native forests through the 20th century, Hawaii's native damselflies, including the two species that are the subject of this final listing action, experienced a tremendous reduction in available habitat. In addition, predation by a number of nonnative species that have been both intentionally and, in some cases, inadvertently introduced into the Hawaiian Islands is a significant and ongoing threat to all native Hawaiian damselflies.

Previous Federal Actions

Both the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly were first designated as candidate species on May 22, 1984 (49 FR 21664). Candidate species are those taxa for which the Service has sufficient information on their biological status and threats to propose them for listing under the Act (16 U.S.C. 1531 *et seq.*), but for which the development of a listing regulation has been precluded by other higher-priority listing activities. The flying earwig Hawaiian damselfly was removed from the candidate list on November 21, 1991 (56 FR 58804), whereas the Pacific Hawaiian damselfly retained its status as a candidate species. On November 15, 1994 (59 FR 58982), the flying earwig Hawaiian damselfly was added back onto the candidate list. In the Candidate Notice of Review (CNOR) published on February 28, 1996 (61 FR 7595), we announced a revised list of plant and animal taxa that we regarded as candidates for possible addition to the Lists of Threatened and Endangered Wildlife and Plants. This revision also included a new ranking system, whereby each candidate species was assigned a Listing Priority Number (LPN) from 1 to 12. Both the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly were assigned an LPN of 2 on February 28, 1996 (61 FR 7595).

On May 4, 2004, the Center for Biological Diversity petitioned the Secretary of the Interior to list 225 species of plants and animals that were already candidates, including these two Hawaiian damselfly species, as endangered or threatened under the provisions of the Act. In our annual CNOR, dated May 11, 2005 (70 FR 24870), we retained a listing priority number of 2 for both of these species in accordance with our listing priority guidance published on September 21, 1983 (48 FR 43098). A listing priority number of 2 reflects threats that are both imminent and high in magnitude, as well as the taxonomic classification of each of these two Hawaiian damselflies as distinct species. At the time, we determined that publication of a proposed rule to list these species was precluded by our work on higher priority listing actions. Since then, we have published our annual findings on the May 4, 2004, petition (including our findings on these two candidate species) in the CNORs dated September 12, 2006 (71 FR 53756), December 6, 2007 (72 FR 69034), and December 10, 2008 (73 FR 75176).

In fiscal year 2007, we determined that funding was available to initiate work on listing determinations for these two species. On July 8, 2009, we published a proposed rule to list the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly as endangered (74 FR 32490). We solicited data and comments from the public on the proposed rule for 60 days, ending September 8, 2009. To allow the public and interested parties additional time to submit comments on the proposed rule, we reopened the comment period on November 19, 2009 (74 FR 59956), and accepted comments until December 21, 2009.

Species Information

Flying Earwig Hawaiian Damselfly

The flying earwig Hawaiian damselfly was first described from specimens collected in the 1890s in Puna on Hawaii Island by R.C.L. Perkins (1899, p. 72). Kennedy (1934, pp. 343-345) described what was believed at the time to be a new species of damselfly based on specimens from Maui; these were later determined to be synonymous with the specimens collected by Perkins. The flying earwig Hawaiian damselfly is a comparatively large and elongated species. The males are blue and black in color and exhibit distinctive, greatly enlarged, pincer-like cerci (paired appendages on the rearmost segment of the abdomen used to clasp the female during mating). It is for the males' elongated abdominal appendages and their resemblance to those found on earwigs (order Dermaptera) that the species is named. Females are predominantly brownish in color. The adults measure from 1.8 to 1.9 inches (in) (46 to 50 millimeters (mm)) in length and have a wingspan of 1.9 to 2.1 in (50 to 53 mm). The wings of both sexes are clear except for the tips, which are narrowly darkened along the front margins. Naiads of this species have never been collected or found (Polhemus and Asquith 1996, p. 69), but they are believed to be terrestrial or semiterrestrial in habit (Kennedy 1934, p. 345; Preston 2007a).

The biology of the flying earwig Hawaiian damselfly is not well understood, and it is unknown if this species is more likely to be associated with standing water or flowing water (Kennedy 1934, p. 345; Polhemus 1994, p. 40). The only confirmed population found in the last 6 years occurs along a single East Maui stream and the adjacent steep, moist, riparian talus slope (a slope formed by an accumulation of rock debris), which is densely covered with *Dicranopteris*

linearis (uluhe), a native fern. Adults of the flying earwig Hawaiian damselfly have been observed to perch on vegetation and boulders, and to fly slowly for short distances above this particular stream within the one known remaining habitat site. When disturbed, the adults fly downward within nearby vegetation or between rocks, rather than up and away as is usually observed with aquatic Hawaiian damselfly species. Although immature individuals have not been located, based on the habitat and the behavior of the adults, it is believed that the naiads may be terrestrial or semiterrestrial, occurring among damp leaflitter (Kennedy 1934, p. 345) or possibly within moist soil or seeps between boulders in suitable habitat (Preston 2007a). The highest elevation at which this species has been recorded is 3,000 feet (ft) (914 meters (m)), but its close association with uluhe habitat suggests that its range may extend upward to close to 4,000 ft (1,212 m) (Foote 2007).

Historically, the flying earwig Hawaiian damselfly was known from the islands of Hawaii and Maui. On Hawaii, it was originally known from seven or more general localities. The species has not been seen on Hawaii for over 80 years, although extensive surveys within apparently suitable habitat in the Kau and Olaa areas were conducted from 1997 to 2008 (Polhemus 2008). On Maui, the flying earwig damselfly was historically reported from five general locations on the windward side of the island (Kennedy 1934, p. 345). Since the 1930s, however, the flying earwig Hawaiian damselfly has only been observed in a single area along a particular stream on the windward side of east Maui, despite surveys from 1993 through 2008 at several of its historically occupied sites. Although presumed extant, the last observation of the species was in 2005 (Foote 2008); the species was not observed during the last survey at this location in 2008. No quantitative estimate of the size of this remaining population is available.

It is hypothesized that the flying earwig Hawaiian damselfly may now be restricted to what is perhaps suboptimal habitat, where periodic absences of the species due to drought may be expected and might explain the lack of observations of the species (Foote 2007). Some researchers also believe that overcollection of this species by enthusiasts may have impacted some populations in the past (Polhemus 2008). It is further possible that the individuals observed in this area are actually part of a larger population that may be located in the extensive belt of uluhe habitat located upslope, where the habitat is predominantly native shrubs and matted fern understory (Foote 2007; Hawaii Biodiversity and Mapping Program (HBMP) 2006). Unsurveyed areas containing potentially suitable habitat for this species include the Hana coast of east Maui, and the east rift zone of Kilauea and the Kona area on the island of Hawaii (Foote 2007).

Pacific Hawaiian Damselfly

The Pacific Hawaiian damselfly was first described by McLachlan (1883, p. 234), based on specimens collected by R.C.L. Perkins from streams on the islands of Lanai and Maui. This damselfly is a relatively small, dark-colored species, with adults measuring 1.3 to 1.4 in (34 to 37 mm) in length and having a wingspan of 1.3 to 1.6 in (33 to 42 mm). Both adult males and females are mostly black in color. Males exhibit brick-red striping and patterns, while females exhibit light-green striping and patterns. The only immature individuals of this species that have been collected were early-instar (an intermoult stage of development) individuals, and they exhibit flattened, leaf-like gills (Polhemus and Asquith 1996, p. 83). This species is most easily distinguished from other Hawaiian damselflies by the extremely long lower abdominal appendages of the male, which greatly exceed the length of the upper appendages.

Historically, the Pacific Hawaiian damselfly was known from lower elevations (below 2,000 ft (600 m)) on all of the main Hawaiian Islands except Kahoolawe and Niihau (Perkins 1899, p. 64). This species was known to breed primarily in lentic (standing water) systems such as marshes, seepage-fed pools, large ponds at higher elevations, and small, quiet pools in gulches that have been cut off from the main stream channel (Moore and Gagne 1982, p. 4; Polhemus and Asquith 1996, p. 83). The Pacific Hawaiian damselfly is no longer found in most lentic habitats in Hawaii, such as ponds and taro (*Colocasia esculenta*) fields, due to predation by nonnative fish that now occur in these systems (Moore and Gagne 1982, p. 4; Englund *et al.* 2007, p. 215). Observations have confirmed that the Pacific Hawaiian damselfly is now restricted almost exclusively to seepage-fed pools along overflow channels in the terminal reaches of perennial streams, usually in areas surrounded by thick vegetation (Moore and Gagne 1982, pp. 3-4; Polhemus 1994, p. 54; Englund 1999, p. 236; Englund *et al.* 2007, p. 216; Polhemus 2007, p. 238). Adults usually do not stray far from the vicinity of the breeding pools, perching on bordering vegetation and flying only short distances when disturbed (Polhemus and Asquith 1996, p. 83). This species is rarely seen along main stream channels, and its ability to disperse long distances over land or water is suspected to be poor compared to other Hawaiian damselflies (Jordan *et al.* 2007, p. 254).

The Pacific Hawaiian damselfly is now believed to be extirpated from the islands of Oahu, Kauai, and Lanai (Polhemus and Asquith 1996, p. 83). On the island of Oahu, due to its occupation of particularly vulnerable habitat within sidepools of lowland streams, the Pacific Hawaiian damselfly was rare by the 1890s and appears to have been extirpated from this island by 1910 (Liebherr and Polhemus 1997, p. 494). It is unknown when the Kauai and Lanai populations of the Pacific Hawaiian damselfly disappeared. Until 1998, it was believed that the species was extirpated from the island of Hawaii. That year, one population was discovered within a small stream located just above, but isolated from, Maili Stream, which is known to be occupied by nonnative fish (Englund 1998, pp. 15-16). On Maui and Molokai, fewer than six populations of the Pacific Hawaiian damselfly could be located by the 1970s (Harwood 1976, pp. 251-253; Gagne 1980, pp. 119, 125; Moore and Gagne 1982, p. 1). The conservation of this species was identified as a priority by the International Union for the Conservation of Nature and Natural Resources (Moore 1982, p. 209).

The Pacific Hawaiian damselfly is currently found in at least seven streams on Molokai and may possibly be extant in other unsurveyed streams on Molokai's northern coast that have not been invaded by nonnative fish (Englund 2008). On the island of Maui, the species is currently known from 14 streams. The Pacific Hawaiian damselfly is no longer found along the entire reaches of these Maui streams, but only in restricted areas along each stream where steep terrain prevents access by nonnative fish, which inhabit degraded, lower stream reaches (Polhemus and Asquith 1996, p. 13; Englund *et al.* 2007, p. 215). The species is known from a single population on the island of Hawaii, last observed in 1998.

No quantitative estimates of the size of the extant populations are available. Howarth (1991, p. 490) described the Pacific Hawaiian damselfly as the most common and most widespread of the native damselfly species at the end of the 19th century, and yet a decline in this species was observed as early as

1905 due to the effects of nonnative fish introduced for control of mosquitoes.

Summary of Comments and Recommendations

In our proposed rule published on July 8, 2009 (74 FR 32490), we requested that all interested parties submit written comments on the proposal by September 8, 2009. We also contacted appropriate Federal and State agencies, scientific experts and organizations, and other interested parties and invited them to comment on the proposal. Newspaper notices inviting general public comment were published on the islands of Hawaii, Maui, Molokai, and Oahu. On November 19, 2009 (74 FR 59956), we reopened the comment period for an additional 30 days, ending December 21, 2009.

We received a total of five written comments and no requests for public hearings. Three comments were from State of Hawaii agencies and two were from the same nongovernmental organization. We received three comments supporting the listing of the two Hawaiian damselflies. Two comments neither supported nor opposed the listings, and one of these comments provided additional information on the two damselflies. We also requested peer review from potential peer reviewers.

Peer Review Comments

In accordance with our peer review policy published on July 1, 1994 (59 FR 34270), we solicited expert opinion from seven knowledgeable individuals with scientific expertise that included familiarity with the two Hawaiian damselflies and their habitat, biological needs, and threats. We received no written comments from any of the seven peer reviewers, although several offered their opinion that the two Hawaiian damselfly species meet the definition of an endangered species (A. Asquith, Hawaii Sea Grant, pers. comm. 2009; F. Howarth, Bishop Museum, pers. comm. 2009; K. Magnacca, University of Hawaii at Hilo, pers. comm. 2009; D. Polhemus, State of Hawaii Division of Aquatic Resources, pers. comm. 2009; D. Preston, Bishop Museum, pers. comm. 2009).

Comments from the State of Hawaii

The State of Hawaii's State Historic Preservation Division concurred that no historic properties would be affected by the listing of the two Hawaiian damselflies (McMahon 2009, pers. comm.). The State's Division of Forestry and Wildlife (DOFAW) and Office of Hawaiian Affairs supported listing the two damselflies as endangered (Conry 2009, pers. comm.; Namu'o 2009, pers. comm.).

Public Comments

(1) *Comment*: One commenter stated that there appears to be little, if any, empirical data indicating water diversions have any potential impact on the flying earwig Hawaiian damselfly.

Our response: While we acknowledge that the larval stage of the flying earwig Hawaiian damselfly has never been observed within stream water, repeated observations of the adults along the stream adjacent to its only known population site on east Maui indicate a strong biological association of an unknown nature with flowing stream water. This association is likely related to the species' natural history and may include the need for sufficient space or a stream setting for mating adults and territorial behavior of males. Additionally, the species' larval habitat is undoubtedly dependent on localized area hydrology. For example, should a stream experience either reduced flow or complete dewatering for an extended period of time, it is expected that the impact to surrounding soils and associated vegetation, including the uluhe ferns that are believed to be the species' likely larval-stage habitat, will be soil desiccation and concomitant prolonged vegetation dieback, resulting in degraded habitat conditions for the flying earwig Hawaiian damselfly.

(2) *Comment*: One commenter stated the reduction or modification of water flow in a stream should not be identified as an activity that could potentially result in violation of section 9 of the Act pertaining to the flying earwig Hawaiian damselfly.

Our response: As discussed in the previous response (see *Comment* 1), we believe there is a strong association with stream water flow and the species' life history requirements. Stream flow is likely essential to the adult damselfly's breeding requirements and is also essential to maintaining localized soil hydrology necessary for persistence of uluhe ferns, which are known foraging and mating sites for the adults and may provide habitat for the larval stage. Therefore, any permanent or prolonged reduction or modification of stream flow in a stream utilized by this species may result in a violation of section 9 of the Act.

(3) *Comment*: One commenter stated that distribution of both species is not fully known and recommended that the Service conduct additional surveys for both species prior to proceeding with listing.

Our response: In preparing both the proposed and final rules for these species, we reviewed the best scientific and commercial data available, including technical reports, published journal articles, and numerous other documents, including unpublished reports and surveys. In addition, we consulted with several species experts. We based our listing determination for the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly on the best available information regarding the species' current known population status, the known condition of their habitat, and the current factors affecting the species, along with ongoing conservation efforts, as described in the **Summary of Factors Affecting the Species** (below) in this final rule. The Act neither provides for, nor requires, additional research effort prior to a listing decision. We acknowledge that uncertainties exist; however, under section 4 of the Act, we must make a listing determination based on the best scientific and commercial available at the time of our determination.

(4) *Comment*: One commenter disagreed with our analysis that stream diversions for agriculture have reduced stream habitat available to the Pacific Hawaiian damselfly, and currently pose a threat to this species.

Our response: Historically, the impacts of the plantation-era sugarcane irrigation system reduced stream habitat available to this species. The Pacific Hawaiian damselfly was once among the most commonly observed aquatic insects in the islands (Zimmerman 1948, p. 377). Because this species breeds in lentic habitats or stream terminal reaches, which experienced significant modification for agriculture beginning as early as the 19th century, the Pacific Hawaiian damselfly was extirpated from many of its historical habitat sites (Polhemus 2007, p. 236). By the 1930s, water diversions had been developed on all of the main Hawaiian Islands, and by 1978, the stream flow in over one-half of all of the 366 perennial streams in Hawaii had been altered in some manner (Brasher 2003, p. 1055). All or most of the low or average flow of the stream was, and often still is, diverted into fields or reservoirs, leaving many stream channels completely dry (Takasaki *et al.* 1969, pp. 27-28; Harris *et al.* 1993, p. 12; Wilcox 1996, p. 56).

With the nearly complete cessation of this industry in the Hawaiian Islands, it is unlikely that new irrigation-related water diversion activities will be initiated in the remaining streams that currently provide habitat for the Pacific Hawaiian damselfly. However, most of the historical water diversions remain in

place. The historical loss of stream habitat, resulting in the present curtailment of habitat available to the Pacific Hawaiian damselfly, combined with the threat of predation by nonnative fish in the remaining stream habitat, continues to restrict and reduce the amount of habitat potentially available to this species. Should some of this water be returned to stream systems, the amount of habitat available to this species may increase if the water return were to be implemented carefully to prevent the spread of nonnative fish species upstream.

(5) *Comment*: One commenter noted the Pacific Hawaiian damselfly, although historically known from lower elevations, is now known to have established successfully breeding populations at higher elevations above existing stream diversions.

Our response: Prior to the establishment of widespread stream diversions, the Pacific Hawaiian damselfly was considered one of the most abundant and frequently observed insects in Hawaii and was known from all of the main Hawaiian Islands, except Kahoolawe and Niihau. Previously known from suitable portions of many streams and water bodies from sea level to some higher elevation sites (Zimmerman 1948, p. 377), the Pacific Hawaiian damselfly is now extirpated from at least 18 known population sites on the islands of Hawaii, Kauai, Lanai, Oahu, Maui, and Molokai. Diversions changed the amount and flow rate of water within many lower stream sections, because the diversions either reduced the amount of water flow at the point of diversion, or captured all stream water (as they were designed to do) during times of drier weather or drought. The Pacific Hawaiian damselfly is currently found in approximately 22 streams on the islands of Hawaii, Maui, and Molokai, across a variety of elevations. All known populations are located within streams or bodies of water free of nonnative, predatory fish. We lack sufficient information to determine whether all stream reaches occupied by this damselfly species are now above manmade diversions, but we know the species is largely absent from areas below manmade diversions.

(6) *Comment*: One commenter stated that the current known range of the Pacific Hawaiian damselfly appears to be broader than the species' known range at the time it became a candidate for listing.

Our response: We acknowledged in our proposed rule that at the time we determined we had sufficient information on file to support a proposal to list the Pacific Hawaiian damselfly (1984), and elevated it to candidate status, it had been extirpated from Kauai, Oahu, and Lanai, and was also considered extirpated from the island of Hawaii. Subsequently in 1998, a single population was discovered on an isolated portion of a Hilo stream on the island of Hawaii. However, since then, the Pacific Hawaiian damselfly has not been reobserved on Kauai, Lanai, or Oahu, and remains only on Molokai and Maui, and one location on Hawaii Island. We do not consider the discovery of a single population on the island of Hawaii to represent a significant broadening of the range of the species.

(7) *Comment*: One commenter observed that water diversions may enhance the damselflies' chances for survival by isolating them from predatory, nonnative fish species.

Our response: We agree that existing diversions on some streams function as a manmade barrier and prevent the egress of nonnative, predatory fish into currently isolated, upstream damselfly habitat sites. However, existing diversions also alter the historical amount and flow rate of water within many lower stream sections because the diversions either reduce the amount of water flow at the point of diversion or capture all stream water during times of drier weather or drought. Therefore, the net impact of stream diversions in the Hawaiian Islands has been and continues to be an overall reduction in the amount of suitable stream habitat available to both the Pacific Hawaiian damselfly and the flying earwig Hawaiian damselfly.

(8) *Comment*: One commenter noted that the recently mandated interim in-stream flow standards (IIFS) established by the Commission for Water Resource Management (CWRM) for 10 east Maui streams diverted by the East Maui Irrigation Company (EMI) may either benefit existing damselfly populations or allow entry of nonnative fish species into currently fish-isolated damselfly habitat. The commenter further stated that the proposed rule incorrectly identifies the 1988 IIFS as current while newer standards have been mandated.

Our response: We agree that the potential release of additional water into streams that are currently being diverted is a complex issue, and that the outcome may be beneficial to damselflies or may increase the threat from nonnative predatory fish. As of the date of publication of this final rule, it is our understanding that the recently proposed IIFS have yet to be approved and implemented by the CWRM, and we therefore recognize the 1988 standards as current. Because the new standards have not yet been implemented, we are unable to determine their effectiveness in enhancing damselfly habitat.

Should the proposed IIFS be approved as the new standard, we will strongly support a collaborative conservation effort between our agency; the State; the CWRM; and affected landowners, leaseholders, and other entities, to analyze the potential return of water flow into currently diverted streams on a case-by-case basis, to ensure the protection of the Pacific Hawaiian and the flying earwig Hawaiian damselflies and their stream or stream-associated habitat.

(9) *Comment*: One commenter disagreed with our assessment that the damselflies were threatened by inadequate regulatory protections. The commenter stated that the State Water Code requires that the economic benefits of stream water removal be balanced against in-stream benefits, including benefits to aquatic fish and wildlife. The commenter further stated that the CWRM's IIFS standards provide adequate protection for aquatic wildlife, and the CWRM has, in the past, given considerable deference to in-stream benefits over stream water removal in setting IIFS.

Our response: We believe that the CWRM's stated requirements to provide protection for aquatic wildlife are insufficiently specific to adequately protect the damselflies or their habitat. The CWRM's IIFS standards do not include provisions that address the needs of the species. Additionally, we lack specific examples of past CWRM deference to in-stream benefits, and are thus unable to determine whether CWRM's IIFS standards have specifically benefited these damselflies.

(10) *Comment*: One commenter explained that several of the State's existing hydroelectric plants do not operate directly on streams but are located some distance away and are powered by water diverted from streams.

Our response: In this final rule, we have clarified that water is diverted to power hydroelectric facilities regardless of their location.

(11) *Comment*: One commenter noted that some of the hydroelectric projects identified as proposed may be developed without diverting additional water from streams.

Our response: We have modified the appropriate section of this final rule to clarify that in some cases, for some of the State's proposed hydroelectric facilities, no additional water might be diverted beyond what is currently removed for agriculture or other

purposes. However, the threats to the damselflies below the point of diversion within a given stream remain the same due to the existing diversion, and we believe that any additional increased water diversion for hydroelectric power could possibly impact damselfly populations.

(12) *Comment*: One commenter noted that water currently being diverted from streams to generate power for some hydroelectric projects is often returned downstream within the same stream system. Therefore, the potential to impact damselfly habitat will vary depending on location of the diversion and location of damselfly habitat within the respective stream system.

Our response: We have modified the appropriate section of this final rule to clarify that, in some streams, water diverted for the generation of power is returned to the same stream system. However, the threats to the damselflies below the point of diversion remain, and may depend upon the difference (if any) of the volume and quality of water returned and the point at which the water is returned to the stream system. The commenter did not provide specific examples or elaborate upon specific streams.

(13) *Comment*: One commenter clarified that the Hawaii Stream Assessment (HSA) (CWRM 1990) identifies 28, not 38, sites that have potential to be developed for hydropower. The commenter further noted that these sites have not been proposed for development, but rather that the sites have been identified as economically developable for hydroelectric use. Populations of the Pacific Hawaiian damselfly are located upon three of these streams identified only as potentially economically developable for hydroelectric use.

Our response: We have modified the appropriate section of this final rule to correct the information that 28, not 38, sites have been identified as potentially economically developable for hydroelectric use and that three of the streams harboring Pacific Hawaiian damselfly populations are not proposed for development but rather are identified as only potentially developable.

(14) *Comment*: One commenter observed that the HSA identifies 10 sites where hydropower developments have been proposed, several of which overlap with sites identified as potentially developable (see *Comment* 13). The commenter further noted that the list of 10 sites actually proposed for hydroelectric development does not include streams known to be occupied by the Pacific Hawaiian damselfly; therefore, future hydropower development is unlikely to impact this species. However, one proposed site does include the only known population of the flying earwig Hawaiian damselfly.

Our response: We have modified the appropriate section of this final rule to clarify that some of the 10 sites proposed for development in the HSA overlap with those sites identified as economically developable, and that none of the 10 proposed sites includes streams with Pacific Hawaiian damselfly populations. We have added the information regarding the proposed hydroelectric development on the stream site associated with the only known location of the flying earwig Hawaiian damselfly to our threats analysis (see *Factor A*).

Summary of Factors Affecting the Species

Section 4 of the Act (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR part 424) set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act. These five listing factors are: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; and (E) other natural or manmade factors affecting its continued existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination.

The threats to the flying earwig and Pacific Hawaiian damselfly species are summarized according to the five listing factors in Table 1, and discussed in detail below.

TABLE 1. SUMMARY OF THREATS TO THE FLYING EARWING HAWAIIAN DAMSELFLY AND PACIFIC HAWAIIAN DAMSELFLY.

5 FACTORS CATEGORY	THREATS	SPECIES	
		Flying Earwig Hawaiian Damselfly	Pacific Hawaiian Damselfly
FACTOR A	Agriculture/urban development	X	X
	Stream alteration	P	X
	Habitat modification by pigs	X	—
	Habitat modification by nonnative plants	X	X
	Stochastic events	X	X
	Climate change	P	P
FACTOR B	Overcollection	P	—
FACTOR C	Predation	A, BF (P)	A, B, F, BF
FACTOR D	Inadequate habitat protection	X	X
	Inadequate protection from nonnative aquatic species	X	X
FACTOR E	Limited populations	X	X

A = ants

B = backswimmers
F = fish
BF = bullfrogs
P = potential threat
X = known threat

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Freshwater habitats used by the flying earwig and Pacific Hawaiian damselflies on all of the main Hawaiian Islands are severely altered and degraded because of past and present land and water management practices, including: agriculture and urban development; development of groundwater, perched aquifer (aquifer sitting above main water table), and surface water resources; and the deliberate and accidental introductions of nonnative animals (Harris *et al.* 1993, pp. 12-13; Meier *et al.* 1993, pp. 181-183).

Habitat Destruction and Modification by Agriculture and Urban Development

Although there has not been a comprehensive, site-by-site assessment of wetland loss in Hawaii (Erikson and Puttock 2006, p. 40), Dahl (1990, p. 7) estimated that at least 12 percent of lowland to upper-elevation wetlands in Hawaii had been converted to non-wetland habitat by the 1980s. If only coastal plain (below 1,000 ft (305 m) elevation) wetlands are considered, it is estimated that 30 percent have been converted for agricultural and urban development (Kosaka l990, p. 1). These marshlands and wetlands provided habitat for several damselfly species, including the Pacific Hawaiian damselfly.

By the 1930s, water diversions had been developed on all of the main Hawaiian Islands, and by 1978, the stream flow in over one-half of all of the 366 perennial streams in Hawaii had been altered in some manner (Brasher 2003, p. 1055). All or most of the low or average flow of the stream was, and often still is, diverted into fields or reservoirs, leaving many stream channels completely dry (Takasaki *et al.* 1969, pp. 27-28; Harris *et al.* 1993, p. 12; Wilcox 1996, p. 56). The historical destruction and modification of habitat continues to impact the two Hawaiian damselflies, by restricting them to curtailed or isolated habitat areas that are often degraded in quality (for example, by the presence of predatory nonnative fishes). The present curtailment of the habitat or range of the flying earwig Hawaiian damselfly and Pacific Hawaiian damselfly due to past habitat destruction or modification in turn limits population size, distribution, and connectivity, resulting in an increased probability of local extirpation or even extinction of the two Hawaiian damselfly species.

Although extensive filling of freshwater wetlands is rarely permitted today, loss of riparian or wetland habitats utilized by the Pacific and flying earwig Hawaiian damselflies, such as smaller areas of moist slopes, emergent vegetation, and narrow strips of freshwater seeps within anchialine pool complexes (landlocked bodies of water with a subterranean connection to the ocean), still occurs. In addition, marshes have been, and continue to be, slowly filled and converted to meadow habitat due to increased sedimentation resulting from increased storm water runoff from upslope development, the accumulation of uncontrolled growth of invasive vegetation, and blockage of downslope drainage (Wilson Okamoto & Associates, Inc. 1993, pp. 3-4 to 3-5).

The effects of future conversion of wetland and other aquatic habitat for agriculture and urban development are immediate and significant for the following reason: As noted above, an estimated 30 percent of all coastal plain wetlands in Hawaii have already been lost to agriculture and urban development, while the loss of lowland freshwater habitat in Hawaii already approaches 80 to 90 percent (Kosaka 1990, p. 1). Lacking the aquatic habitat features that the damselflies require for essential life history needs, such as marshes, ponds, and sidepools along streams (Pacific Hawaiian damselfly) and riparian habitat (flying earwig Hawaiian damselfly), these modified areas no longer support populations of these two Hawaiian damselflies. Agriculture and urban development have thus contributed to the present curtailment of the habitat of these two Hawaiian damselflies, and we have no indication that this threat is likely to be significantly ameliorated in the foreseeable future.

Habitat Destruction and Modification by Stream Diversion

Stream modifications began with the early Hawaiians, who diverted water to irrigate taro. However, unlike modern stream diversions which often completely dewater streams all year around, early diversions often took no more than half the stream flow, and typically were periodic to occasionally flood taro ponds at different times through the year, rather than continuously flood them (Handy and Handy 1972, pp. 58-59). The advent of plantation sugarcane cultivation led to far more extensive stream diversions, with the first diversion built in 1856 on Kauai (Wilcox 1996, p. 54). These systems were designed to tap water at upper elevations (above 984 ft (300 m)) by means of a concrete weir in the stream (Wilcox 1996, p. 54). All or most of the low or average flow of the stream was, and often still is, diverted into fields or reservoirs, leaving many stream channels completely dry (Takasaki *et al.* 1969, pp. 27-28; Harris *et al.* 1993, p. 12; Wilcox 1996, p. 56).

As noted above, by the 1930s, water diversions had been developed on all of the main Hawaiian Islands, and by 1978, the stream flow in over one-half of all of the 366 perennial streams in Hawaii had been altered in some manner (Brasher 2003, p. 1055). Some stream diversion systems are extensive, such as the Waiahole Ditch, which diverts water from 37 streams within the range of the Pacific Hawaiian damselfly on the windward side of Oahu to the dry plains on the leeward side of the island via a tunnel cut through the Koolau mountain range (Stearns and Vaksvik 1935, pp. 399-403). On west Maui, as of 1978, over 49 miles (mi) (78 kilometers (km)) of stream habitat in 12 streams had been lost due to diversions, and all of the 17 perennial streams on west Maui are dewatered to some extent (Maciolek 1979, p. 605). This loss of stream habitat may have contributed to the extirpation of the Pacific Hawaiian damselfly population on west Maui. Given the affiliation of the flying earwig Hawaiian damselfly with riparian habitats, this loss of stream habitat may also potentially account for its absence on west Maui. Most lower-elevation stream segments on west Maui are now completely dry, except during storm-influenced flows (Maciolek 1979, p. 605).

The maintenance of natural hydrology is closely tied to the life history requirements of the Hawaiian damselflies, as the presence of standing or running water is essential to reproduction of the two species. In addition to providing breeding habitat for the adults, the aquatic larval stage of the Pacific Hawaiian damselfly is entirely dependent on water, and the maintenance of local soil hydrology is necessary for the persistence of uluhe

ferns, which provide habitat for the larval stage of the flying earwig Hawaiian damselfly. The reduced flow or complete dewatering of streams thus results in the destruction or degradation of habitat conditions for both the Pacific and flying earwig Hawaiian damselflies. The extensive diversion of streams on Maui island-wide has reduced the amount of stream habitat available to the Pacific Hawaiian damselfly, and potentially to the flying earwig Hawaiian damselfly as well.

In addition to diverting water for agriculture and domestic water supply, streams in Hawaii have also been diverted for use in hydroelectric power. In some cases, the water used for power generation is already being diverted for another use; in other cases the water is returned to the stream of origin. There are a total of 18 active hydroelectric plants operating on Hawaiian streams on the islands of Hawaii, Kauai, and Maui, only one of which is located on a stream where a historical population of the Pacific Hawaiian damselfly was known on Kauai (Waimea). Another 28 sites have been identified as feasible for hydroelectric development on the islands of Hawaii, Kauai, Maui, and Molokai (Hawaii Stream Assessment 1990, pp. xxi, 96-97). Three of the sites identified as developable include current populations of the Pacific Hawaiian damselfly. A total of 10 streams have actually been proposed for development, with some overlap between the 28 streams identified as feasible. Notably, the stream adjacent to the single current remaining population site for the flying earwig Hawaiian damselfly on Maui is included among those proposed for hydroelectric development. Any additional diversion of stream flow for use in hydroelectric power could contribute to further loss of stream habitat for the Pacific Hawaiian damselfly and for the flying earwig Hawaiian damselfly.

Habitat Modification and Destruction by Dewatering of Aquifers

In addition to the diversion of stream water and the resultant downstream dewatering, many streams in Hawaii have experienced reduced or zero surface flow as a result of the dewatering of their source aquifers. Often these aquifers, which previously fed the streams, were tapped by tunneling or the injudicious placement of wells (Stearns and Vaksvik 1935, pp. 386-434; Stearns 1985, pp. 291-305). These groundwater sources were captured for both domestic and agricultural use and in some areas have completely depleted nearby stream and spring flows. For example, the Waikolu Stream on Molokai has reduced flow due in part to groundwater withdrawal (Brasher 2003, p. 1,056), which may have reduced stream habitat available to the Pacific Hawaiian damselfly. Likewise, on Maui, streams in the west Maui Mountains that flow into the Lahaina District are fed by groundwater leaking from breached high-elevation dikes. Downstream of the dike compartments, stream diversions are designed to capture all of the low stream flow, causing the streams downstream to be frequently dry (U.S. Geological Survey 2008a, p. 1), likely impacting available habitat for the Pacific Hawaiian damselfly, and potentially for the flying earwig Hawaiian damselfly, in the Honolua and Honokohau streams.

The island of Lanai lies within the rain shadow of the west Maui Mountains, which reach 5,788 ft (1,764 m) in elevation. Lower in elevation than Maui, annual rainfall on Lanai's summit is 30 to 40 in (760 to 1,015 mm), but is much less over the rest of the island (University of Hawaii Department of Geography 1998, p. 13). Flows of almost every spring and seep on Lanai have been diverted (Stearns 1940, pp. 73-74, 85, 88, 95). Surface waters in streams have also been diverted by tunnels in stream beds. Historically, Maunalei Stream was the only perennial stream on Lanai, and Hawaiians constructed taro loi (ponds for cultivation of taro) in the lower portions of this stream system. In 1911, a tunnel was constructed at 1,100 ft (330 m) elevation that undercuts the stream bed, diverting both the surface and subsurface flows and dewatering the stream from this point to its mouth (Stearns 1940, pp. 86-88). The Pacific Hawaiian damselfly, which depends on stream habitat, was historically known from Lanai but is no longer extant on this island. The Pacific Hawaiian damselfly was most likely impacted by the dewatering of this stream because it was the only permanent stream on Lanai prior to its dewatering. This example of the negative impact of dewatering leads us to conclude that dewatering poses a threat to the Pacific Hawaiian damselfly and the flying earwig Hawaiian damselfly on the remaining islands where the species persist.

Habitat Modification and Destruction by Vertical Wells

Surface flow of streams has also been affected by vertical wells drilled in the past, because the basal aquifer (lowest groundwater layer) and alluvial caprock (sediment-deposited harder rock layer) through which the lower sections of streams flow can be pierced and hydraulically connected by wells (Stearns 1940, p. 88). This allows water in aquifers normally feeding the stream to be diverted elsewhere underground. Dewatering of the streams by tunneling and earlier, less-informed well placement near or in streams was a significant cause of habitat loss, and these effects continue today. Historically, for example, there was sufficient surface flow in Makaha and Nanakuli streams on Oahu to support taro loi in their lower reaches, but this flow disappeared subsequent to construction of vertical wells upstream (Devick 1995, p. 1). The inadvertent dewatering of streams through the piercing of their aquifers (which are normally separated from adjacent water-bearing layers by an impermeable layer), by tunneling or through placement of vertical wells, caused the loss of Pacific Hawaiian damselfly habitat, and contributed to the Pacific Hawaiian damselfly's extirpation on the islands of Oahu, Kauai, and Lanai (Polhemus and Asquith 1996, pp. 23-24). Such activities also reduced the extent of stream habitat for the Pacific Hawaiian damselfly on the islands of Maui, Molokai, and Hawaii. Most lower-elevation stream segments on west Maui and leeward east Maui are now completely dry, except during storm-influenced flows (Maciolek 1979, p. 605). The flow of nearly every seep and spring on Lanai has been captured or bored with wells (Stearns 1940, pp. 73-74, 85, 88, 95). The inadvertent drying of streams from earlier, uninformed well placement and other activities has contributed to the decline of the Pacific Hawaiian damselfly by reducing its habitat on all of the islands from which it was historically known. It should be noted that the Pacific Hawaiian damselfly was once among the most commonly observed aquatic insects in the islands (Howarth 1991, p. 40). The dewatering of streams on Maui and Hawaii may also have impacted habitat of the flying earwig Hawaiian damselfly.

Although the State of Hawaii's Commission on Water Resource Management is now more cognizant of the effects that groundwater removal has on streams via injudicious placement of wells, the Commission still routinely reviews new permit applications for wells (Hardy 2009, p. 1). Thus, the potential for additional well-drilling continues to be a threat (see further discussion under *Factor D, The Inadequacy of Existing Regulatory Mechanisms,* below), and the ongoing effects of previously constructed vertical wells continue to be an ongoing threat to the Hawaiian dragonflies.

Habitat Modification and Destruction by Channelization

In addition to the destruction of most of the stream habitat of the Pacific Hawaiian damselfly and the flying earwig Hawaiian damselfly, much of the remaining stream habitat has been, and continues to be, seriously degraded throughout the Hawaiian Islands. Stream degradation has been particularly severe on the island of Oahu where, by 1978, 58 percent of all the perennial streams had been channelized (lined, partially lined, or altered) to control flooding (Brasher 2003, p. 1055; Polhemus and Asquith 1996, p. 24), and 89 percent of the total length of these streams had been channelized (Parrish *et al.* 1984, p. 83). The channelization of streams creates artificial, wide-bottomed stream beds and often results in removal of riparian vegetation, increased substrate homogeneity, increased temporal water velocity (increased water flow speed during times of higher precipitation, including minor and major flooding), increased illumination, and higher water temperatures (Parrish *et al.* 1984, p. 83; Brasher 2003, p. 1052). Natural streams meander and are lined with rocks, trees, and natural debris, and during times of flooding, jump their banks. Channelized streams are straightened and often lack natural obstructions, and during times of higher precipitation or flooding, facilitate a higher water flow velocity. Hawaiian damselflies are largely absent from channelized portions of streams (Polhemus and Asquith 1996, p. 24). In contrast, undisturbed Hawaiian stream systems exhibit a greater amount of riffle habitat, canopy closure, higher consistent flow velocity, and lower water temperatures that are characteristic of streams to which the Hawaiian damselflies, in general, are adapted (Brasher 2003, pp. 1054-1057).

Channelization of streams has not been restricted to lower stream reaches. For example, there is extensive channelization of the Kalihi Stream, on the island of Oahu, above 1,000-ft (300-m) elevation. Extensive stream channelization has contributed to the extirpation of the Pacific Hawaiian damselfly on Oahu (Englund 1999, p. 236; Polhemus 2008, pp. 45-46).

Stream diversion, channelization, and dewatering represent significant and immediate threats to the Pacific Hawaiian damselfly for the following reasons: (1) They reduce the amount and distribution of stream habitat available to this species; (2) they reduce stream flow, leaving lower elevation stream segments completely dry except during storms, or leaving many streams completely dry year-round, thus reducing or eliminating stream habitat; and (3) they indirectly lead to an increase in water temperature that leads to the loss of Pacific Hawaiian damselfly naiads due to direct physiological stress. Because the probability of species extinction increases when ranges are restricted, habitat decreases, and population numbers decline, the Pacific Hawaiian damselfly is particularly vulnerable to extinction due to such changes in its stream habitats.

In addition, stream diversion, dewatering, and vertical wells have the potential to negatively impact, and in some cases may have impacted, the flying earwig Hawaiian damselfly. Stream flow is essential to the adult flying earwig damselfly's breeding requirements and is also essential to maintaining localized soil hydrology necessary for persistence of uluhe ferns, which are known foraging and mating sites for the adults and may provide habitat for the larval stage. Should the species' population site stream experience either reduced flow or complete dewatering for an extended period of time, it is expected that the impact to surrounding soils and associated vegetation, including the uluhe ferns that are believed to be the species' likely larval-stage habitat, will be soil desiccation and prolonged vegetation dieback, respectively.

Habitat Destruction and Modification by Feral Pigs

One of the primary threats to the flying earwig Hawaiian damselfly is the ongoing destruction and degradation of its riparian habitat by nonnative animals, particularly feral pigs (*Sus scrofa*) (Polhemus and Asquith 1996, p. 22; Erickson and Puttock 2006, p. 42). Pigs of Asian descent were first introduced to Hawaii by the Polynesian ancestors of Hawaiians around 400 A.D. (Kirch 1982, pp. 3-4). Western immigrants, beginning with Captain Cook in 1778, repeatedly introduced European strains (Tomich 1986, pp. 120-121). The pigs escaped domestication and successfully invaded all areas, including wet and mesic forests and grasslands, on all of the main Hawaiian Islands.

High pig densities and expansion of their distribution have caused indisputable widespread damage to native vegetation on the Hawaiian Islands (Cuddihy and Stone 1990, p. 63). Feral pigs create open areas within forest habitat by digging up, eating, and trampling native plant species (Stone 1985, p. 263). These open areas become fertile ground for nonnative plant seeds spread through the excrement of the pigs and by transport in their hair (Stone 1985, p. 263). In nitrogen-poor soils, feral pig excrement increases nutrient availability, enhancing establishment of nonnative weeds that are more adapted to richer soils than are native plants (Cuddihy and Stone 1990, p. 65). In this manner, largely nonnative forests replace native forest habitat (Cuddihy and Stone 1990, p. 65). In addition, feral pigs will root and dig for plant tubers and worms in wetlands, including marshes, on all of the main Hawaiian Islands (Erikson and Puttock 2006, p. 42).

In a study conducted in the 1980s on feral pig populations in Kipahulu Valley on Maui, the deleterious effects of feral pig rooting on native forest ecosystems was documented (Diong 1982, pp. 150, 160-167). Rooting by feral pigs was observed to be related to the search for earthworms, with rooting depths averaging 8 in (20 cm), and rooting was found to greatly disrupt the leaf litter and topsoil layers, and contribute to erosion and changes in ground topography. The feeding habits of pigs were observed to create seed beds, enabling the establishment and spread of invasive weedy species such as *Clidemia hirta* (Koster's curse). The study concluded that all aspects of the feeding habits of pigs are damaging to the structure and function of the Hawaiian forest ecosystem (Diong 1982, pp. 160-167).

It is likely that pigs similarly impact the native vegetation used for perching by adult flying earwig Hawaiian damselflies. On Maui, feral pigs inhabit the uluhe-dominated riparian habitat of the flying earwig Hawaiian damselfly. Through their rooting and digging activities, they have significantly degraded and destroyed the habitat of the adult flying earwig Hawaiian damselfly (Foote 2008, p. 1).

In addition to creating conditions that enable the spread of nonnative plant species, Mountainspring (1986, p. 98) surmised that rooting by pigs depresses insect populations that depend upon the ground layer at some life stage or that exhibit diel (day and night) movements. As a result, it is likely that the presumed habitat (seeps or damp leaf litter) of the naiads of the flying earwig Hawaiian damselfly is negatively impacted by feral pig activity, including the uprooting and denuding of native vegetation (Foote 2008, p. 1; Polhemus 2008, p. 48).

Feral pigs are managed as a game animal for public hunting in the more accessible regions of the east Maui watershed (Jokiel 2008, p. 1). This management makes it likely that feral

pigs will continue to exist on Maui, and thus likely that pigs will continue to destroy and degrade habitat of the flying earwig Hawaiian damselfly on the island of Maui.

The effects from introduced feral pigs are immediate and ongoing because pigs currently occur in the uluhe-dominated riparian habitat of the flying earwig Hawaiian damselfly. The threat of habitat destruction or modification from feral pigs is significant for the following reasons: (1) Trampling and grazing directly impact the vegetation used by adult flying earwig Hawaiian damselflies for perching and by the terrestrial or semiterrestrial naiads; (2) increased soil disturbance leads to mechanical damage to plants used by adults for perching and by the terrestrial or semiterrestrial naiads; (3) creation of open, disturbed areas, conducive to weedy plant invasion and establishment of alien plants from dispersed fruits and seeds, results over time in the conversion of a community dominated by native vegetation to one dominated by nonnative vegetation (leading to all of the negative impacts associated with nonnative plants, detailed below); and (4) increased watershed erosion and sedimentation upstream may degrade adult breeding habitat for the flying earwig Hawaiian damselfly. These threats are expected to continue or increase without control or elimination of pig populations in these habitats.

Habitat Destruction and Modification by Nonnative Plants

The invasion of nonnative plants, including *Clidemia hirta* (Koster's curse), further contributes to the degradation of Hawaii's native forests, including the riparian habitat of the flying earwig Hawaiian damselfly on Maui (Foote 2008, p. 1). *Clidemia hirta* is the most serious nonnative plant invader within the uluhe-dominated riparian habitat where the flying earwig Hawaiian damselfly occurs on Maui and where it formerly occurred on the island of Hawaii (Foote 2008, p. 1). A noxious shrub first cultivated in Wahiawa on Oahu before 1941, this plant is now found on all of the main Hawaiian Islands (Wagner *et al.* 1985, p. 41). *Clidemia hirta* forms a dense understory, shading out native plants and hindering their regeneration; it is considered a major nonnative plant threat in wet forest areas because it inhibits and eventually replaces native plants (Wagner *et al.* 1985, p. 41; Smith 1989, p. 64). Invasive nonnatives such as *C. hirta* are capable of modifying the natural environment at the microhabitat level by altering light availability and soil-water regimes, and may eventually replace the native plant community (Cuddihy and Stone 1990, p. 74; Vitousek 1992, pp. 33-35). As *C. hirta* can outcompete the native uluhe fern, this invasive nonnative species poses a threat by altering and degrading the native plant community utilized by the flying earwig Hawaiian damselfly.

Presently, the most significant threat to natural ponds and marshes in Hawaii is the nonnative species *Urochloa mutica* (California grass). This sprawling perennial grass is likely from Africa (Erickson and Puttock 2006, p. 270). It was first noted on Oahu in 1924 and now occurs on all of the main Hawaiian Islands (O'Connor 1999, p. 1,504), where it is considered an aggressive invasive weed of marshes and wetlands (Erickson and Puttock 2006, p. 270). Found from sea level to 3,610 ft (1,100 m) in elevation (Erickson and Puttock 2006, p. 270), this plant forms dense, monotypic stands that can completely eliminate any open water by layering trailing stems (Smith 1985, p. 186). Marshlands eventually convert to meadowland when invaded by *U. mutica* (Polhemus and Asquith 1996, p. 23). At Kawainui Marsh, the most extensive marsh system remaining on Oahu, control of *U. mutica* to prevent conversion of the marsh to meadowland is an ongoing management activity (Wilson, Okamoto and Associates, Inc. 1993, pp. 3-4; Hawaii Ecosystems at Risk (HEAR) 2008, p. 1). The preferred habitat of the Pacific Hawaiian damselfly (primarily lowland, stagnant water, large ponds, and small pools) on all of the Hawaiian Islands has likely declined and continues to decline due to the spread of *U. mutica* (Polhemus and Asquith 1996, p. 23).

In conclusion, nonnative plants represent a significant and immediate and ongoing threat to the flying earwig Hawaiian damselfly through habitat destruction and modification for the following reasons: (1) They adversely impact microhabitat by modifying the availability of light; (2) they alter soil-water regimes; (3) they modify nutrient cycling processes; and (4) they outcompete, and possibly directly inhibit the growth of, native plant species; ultimately, native-dominated plant communities are converted to nonnative plant communities (Cuddihy and Stone 1990, p. 74; Vitousek 1992, pp. 33-35). This conversion negatively impacts and threatens the flying earwig Hawaiian damselfly, which depends upon native plant species, particularly uluhe, for essential life history needs. In addition, conversion of habitat from marshlands to meadowlands caused by the encroachment of the nonnative *Urochloa mutica* threatens the Pacific Hawaiian damselfly. These threats are expected to continue or increase without control or elimination of invasive nonnative plants in these habitats.

Habitat Destruction and Modification by Hurricanes, Landslides, and Drought

Stochastic (random, naturally occurring) events, such as hurricanes, landslides, and drought, alter or degrade the habitat of Hawaiian damselflies directly by modifying and destroying native riparian, wetland, and stream habitats (e.g., rocks and debris falling in a stream, by mechanical damage to riparian and wetland vegetation), and by indirectly by creating disturbed areas conducive to invasion by nonnative plants that outcompete the native plants used by damselflies for perching. We presume these events also alter microclimatic conditions (e.g., opening the tree canopy, leading to an increase in streamwater temperature; increasing stream sedimentation) so that the habitat no longer supports damselfly populations. Both the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly may also be affected by temporary habitat loss (e.g., desiccation of streams, die-off of uluhe) associated with droughts, which are not uncommon on the Hawaiian Islands. With populations that have already been severely reduced in both abundance and geographic distribution, and particularly in the case of the flying earwig Hawaiian damselfly, with only one known population, even such a temporary loss of habitat can have a severe negative impact on the species.

Natural disasters such as hurricanes and drought, and local, random environmental events (such as landslides), represent a significant threat to native riparian, wetland, and stream habitat and the two damselfly species addressed in this final rule. These types of events are known to cause significant habitat damage (Polhemus 1993, p. 86). Because the two species addressed in this final rule now persist in low numbers or occur in restricted ranges, they are more vulnerable to these events and less resilient to such habitat disturbances. Hurricanes, drought, and landslides, even though unpredictable as to exact timing, have been and are expected to continue to be threats to the Hawaiian damselflies. Therefore, they pose immediate and ongoing threats to the two damselfly species and their habitat.

Habitat Destruction and Modification by Climate Change

Currently available information on global climate change is not sufficiently

precise to predict detailed changes in the habitats and ecosystems upon which these species rely. Consequently, the exact nature of the impacts of climate change on the aquatic and riparian habitats of the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly, are unknown. However, increasing temperatures and altered patterns of precipitation may affect aquatic habitats through reduced stream flow, evaporation of standing water, increased streamwater temperature, and the loss of native riparian and wetland plants that comprise the habitat in which these two species occur (Pounds *et al.* 1999, pp. 611-612; Still *et al.* 1999, p. 610; Benning *et al.* 2002, pp. 14,246 and 14,248).

Oki (2004, p. 4) noted long-term evidence of decreased precipitation and stream flow in the Hawaiian Islands, based upon evidence collected by stream gauging stations. This long-term drying trend, coupled with existing ditch diversions and periodic El Niño–caused drying events, has created a pattern of severe and persistent stream dewatering events (Polhemus 2008, p. 52). Future changes in precipitation and the forecast of those changes are highly uncertain because they depend, in part, on how the El Niño–La Niña weather cycle (a disruption of the ocean atmospheric system in the tropical Pacific having important global consequences for weather and climate) might change (Hawaii Climate Change Action Plan 1998, pp. 2-10).

The flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly may be especially vulnerable to extinction due to anticipated environmental change that may result from global climate change. Environmental changes that may affect these species are expected to include habitat loss or alteration and changes in disturbance regimes (e.g., storms and hurricanes), in addition to direct physiological stress caused by increased streamwater temperatures to which the native Hawaiian damselfly fauna are not adapted. The probability of a species going extinct as a result of these factors increases when its range is restricted, habitat decreases, and population numbers decline (Intergovernmental Panel on Climate Change 2007, p. 8). Both of these damselfly species have limited environmental tolerance ranges, restricted habitat requirements, small population size, and a low number of individuals. Therefore, we would expect these species to be particularly vulnerable to projected environmental impacts that may result from changes in climate, and subsequent impacts to their aquatic and riparian habitats (e.g., Pounds *et al.* 1999, pp. 611-612; Still *et al.* 1999, p. 610; Benning *et al.* 2002, pp. 14,246 and 14,248). We believe changes in environmental conditions that may result from climate change will likely impact these two species and, according to current climate projections, we do not anticipate a reduction in this threat any time in the near future; however, the magnitude of this potential threat cannot be determined at this time.

Summary of Factor A

The effects of past, present, and potential future destruction, modification, and degradation of native riparian, wetland, and stream habitats threaten the continued existence of the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly, which depend on these habitats throughout their respective ranges. These effects have been or continue to be caused by: Agriculture and urban development; stream diversion, well-drilling, channelization, and dewatering; introduced feral pigs; introduced plants; and hurricanes, landslides, and drought. The ongoing and likely increasing effects of global climate change, while currently unquantifiable, are also likely to adversely impact, directly or indirectly, the habitat of these two species.

Agriculture and urban development, to date, have caused the loss of 30 percent of Hawaii's coastal plain wetlands and 80 to 90 percent of lowland freshwater habitat in Hawaii. Extensive stream diversions and the ongoing dewatering of remaining wetland habitats continue to degrade the quality of Pacific Hawaiian damselfly habitat and its capability to support viable populations of this species and may also negatively affect the habitat of the flying earwig Hawaiian damselfly. Ongoing habitat destruction and degradation caused by feral pigs in remaining tracts of uluhe-dominated riparian habitat promote the establishment and spread of nonnative plants which, in turn, lower or destroy the capability of the habitat to support viable populations of the flying earwig Hawaiian damselfly. The invasive nonnative grass *Urochloa mutica* threatens to destroy the habitat of the Pacific Hawaiian damselfly through conversion of marshlands to meadowlands.

The above threats have caused the extirpation of many flying earwig Hawaiian damselfly and Pacific Hawaiian damselfly populations; as a result, their current ranges are very restricted. The combination of restricted range, limited habitat quantity and quality, and low population size makes each of these species especially vulnerable to extinction. Thus we consider the present or threatened destruction, modification, or curtailment of the habitat and range of the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly to pose an immediate and significant threat to these species.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Individuals from what may be the single remaining population of the flying earwig Hawaiian damselfly were collected by amateur collectors as recently as the mid-1990s (Polhemus 2008, pp. 14-15). Although it is not known how many individuals were collected at that time, Polhemus (2008, pp. 14-15) inferred that this collection resulted in a noticeable decrease in the population size. Furthermore, if there is only one population of the species left, the decreased reproduction that would result from the removal of potential breeding adults would have a significant negative impact on the species.

There is a market for damselflies that may serve as an incentive to collect them. There are internet websites that offer damselfly specimens or parts (e.g., wings) for sale. In addition, the internet abounds with "how to" guides for collecting and preserving damselfly specimens (e.g., Abbott 2000, pp. 1-3; van der Heijden 2005). After butterflies and large beetles, dragonflies and damselflies are probably the most frequently collected insects in the world (Polhemus 2008, pp. 14-15). A rare specimen such as the flying earwig Hawaiian damselfly may be particularly attractive to potential collectors (Polhemus 2008, pp. 14-15)). Based on the history of collection of the flying earwig Hawaiian damselfly, the market for damselfly specimens or parts, and the vulnerability of this small population to the negative impacts of any collection, we consider the potential overutilization of the flying earwig Hawaiian damselfly to pose an immediate and significant threat to this species.

Unlike the flying earwig Hawaiian damselfly, which is restricted to one remaining population site and which is known to have previously been of interest to odonata enthusiasts (collectors of insects in the order Odonata, including damselflies) (Polhemus 2008, pp. 14-15), we do not believe overcollection is currently a threat to the Pacific Hawaiian damselfly, because it is comparatively more widespread across several population sites on three islands and we are

unaware of hobbyist collection of this species.

Factor C. Disease or Predation

The geographic isolation of the Hawaiian Islands restricted the number of original successful colonizing arthropods and resulted in the development of Hawaii's unusual fauna. Only 15 percent of the known families of insects are represented by native Hawaiian species (Howarth 1990, p. 11). Some groups of insects that often dominate continental arthropod fauna, including social Hymenoptera (e.g., ants and wasps), were absent during the evolution of Hawaii's unique arthropod fauna. Commercial shipping and air cargo, as well as biological introductions to Hawaii, have resulted in the establishment of over 3,372 species of nonnative insects (Howarth 1990, p. 18; Staples and Cowie 2001, p. 52), with an estimated continuing establishment rate of 20 to 30 new species per year (Beardsley 1962, p. 101; Beardsley 1979, p. 36; Staples and Cowie 2001, p. 52).

Nonnative arthropod predators and parasites have also been intentionally imported and released by individuals and governmental agencies for biological control of insect pests. Between 1890 and 1985, 243 nonnative species were introduced, sometimes with the specific intent of reducing populations of native Hawaiian insects (Funasaki *et al.* 1988, p. 105; Lai 1988, pp. 186-187). Nonnative arthropods, whether purposefully or accidentally introduced, pose a serious threat to Hawaii's native insects, including the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly, through direct predation (Howarth and Medeiros 1989, pp. 82-83; Howarth and Ramsay 1991, pp. 81-84; Staples and Cowie 2001, pp. 54-57).

In addition to the problems posed by nonnative arthropods, the establishment of various nonnative fish, frogs, and toads that act as predators on native Hawaiian damselflies has also had a serious negative impact on the Pacific Hawaiian damselfly and flying earwig Hawaiian damselfly, as discussed below.

Predation by Nonnative Ants

Ants are not a natural component of Hawaii's arthropod fauna, and the native species of the islands evolved in the absence of predation pressure from ants. Ants can be particularly destructive predators because of their high densities, recruitment behavior, aggressiveness, and broad range of diet (Reimer 1993, pp. 17-18). The threat of ant predation on the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly is amplified by the fact that most ant species have winged reproductive adults (Borror *et al.* 1989, p. 738) and can quickly establish new colonies in suitable habitats (Staples and Cowie 2001, p. 55). These attributes allow some ants to destroy otherwise geographically isolated populations of native arthropods (Nafus 1993, pp. 19, 22-23).

At least 47 species of ants are known to be established in the Hawaiian Islands (Hawaii Ants 2008, pp. 1-11), and at least 4 particularly aggressive species have severely impacted the native insect fauna, likely including native damselflies (Zimmerman 1948b, p. 173; Reimer *et al.* 1990, pp. 40-43; HEAR database 2005, pp. 1-2): The big-headed ant (*Pheidole megacephala*), the long-legged ant (also known as the yellow crazy ant) (*Anoplolepis gracilipes*), *Solenopsis papuana* (no common name), and *Solenopsis geminata* (no common name). Numerous other species of ants are recognized as threats to Hawaii's native invertebrates, with a trend of new species of ants being established every few years (Staples and Cowie 2001, pp. 53). Due to their preference for drier habitat sites, ants are less likely to occur in high densities in the riparian and aquatic habitat currently occupied by the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly. However, some species of ants (e.g., the long-legged ant and *Solenopsis papuana*) have increased their range into these areas.

The presence of ants in nearly all of the lower elevation habitat sites historically occupied by the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly may preclude the future recolonization of these areas by these two species. Damselfly naiads may be particularly susceptible to ant predation when they crawl out of the water or seek a terrestrial location for their metamorphosis into the adult stage. Likewise, newly emerged adult damselflies are susceptible to predation until their wings have sufficiently hardened to permit flight, or when the adults are simply resting on vegetation at night (Polhemus 2008, p. 59).

The long-legged ant appeared in Hawaii in 1952, and now occurs on Kauai, Oahu, Maui, and Hawaii (Reimer *et al.* 1990, p. 42). It inhabits low to mid-elevation (less than 2,000 ft (600 m)) rocky areas of moderate rainfall (less than 100 in (250 cm) annually) (Reimer *et al.* 1990, p. 42). Direct observations indicate that Hawaiian arthropods are susceptible to predation by this species. Hardy (1979, p. 34) documented the apparent eradication of native insects within the Kipahulu area on Maui after this area was invaded by the long-legged ant. Although only cursory observations exist, long-legged ants are thought to be a threat to populations of the Pacific Hawaiian damselfly in mesic areas within its elevation range due to their particularly aggressive nature and large colony sizes (Foote 2008, p. 1).

Solenopsis papuana is the only abundant, aggressive ant that has invaded intact mesic to wet forest from sea level to over 2,000-ft (600-m) elevation on all of the main Hawaiian Islands, and is still expanding its range (Reimer 1993, p. 14). Gillespie and Reimer (1993, p. 30) found a negative correlation between native spider diversity and areas invaded by this ant species. It is likely, based on our knowledge of the expanding range of this invasive ant, its aggressive nature, and dense populations (Reimer 1993, p. 14), that it may threaten populations of the Pacific Hawaiian damselfly in mesic areas up to 2,000-ft (600-m) elevation as well (Foote 2008, p. 1).

The rarity or disappearance of native damselfly species, including the two species in this final rule, from historical observation sites over the past 100 years, is likely due to a variety of factors. There is no documentation that conclusively ties the decrease in damselfly observations to the establishment of nonnative ants in low to montane, and mesic to wet, habitats on the Hawaiian Islands. However, we do have evidence that introduced ants prey on Hawaiian damselflies. In 1998, during a survey of an Oahu stream, researchers observed predation by ants upon another damselfly species, the orangeblack Hawaiian damselfly (*Megalagrion xanthomelas*) (Englund 2008, pp. 56-57). The presence of nonnative ants in these habitats and parallel decline of damselfly observations in these habitats suggest that nonnative ants may have played a role in the decline of some populations of the flying earwig Hawaiian damselfly and Pacific Hawaiian damselfly.

In summary, observations and reports have documented that ants are particularly destructive predators because of their high densities, broad range of diet, and ability to establish new colonies in otherwise geographically isolated locations, because the reproductive adult ants are able to fly. Damselfly naiads are particularly vulnerable to ant predation when they crawl out of water or seek a terrestrial location for metamorphosis into adults, and newly emerged adults are susceptible to predation until they

can fly. In particular, the long-legged ant and *Solenopsis papuana* are two aggressive species reported from sea level to 2,000-ft (610-m) elevation on all of the main Hawaiian Islands. Since their range overlaps that of both the flying earwig and Pacific Hawaiian damselfly species, we consider these introduced ants to pose an immediate and significant threat to both damselfly species. Unless these aggressive nonnative ant predators are eliminated or controlled, we expect this threat to continue or increase.

Predation by Nonnative Backswimmers

Backswimmers, so called because they swim upside down, are aquatic "true bugs" (Heteroptera). Backswimmers are voracious predators and frequently feed on prey much larger than themselves, such as tadpoles, small fish, and other aquatic insects, including damselfly naiads (Heads 1985, p. 559; Heads 1986, p. 369). Backswimmers are not native to Hawaii, but several species have been introduced. *Notonecta indica* (no common name) was first collected on Oahu in the mid-1980s and is presently known from Oahu, Maui, and Hawaii. Species of *Notonecta* are known to prey on damselfly naiads and the mere presence of this predator in the water can cause naiads to reduce foraging (which can reduce naiad growth, development, and survival) (Heads 1985, p. 559; Heads 1986, p. 369). While there is no documentation that conclusively ties the decrease in damselfly observations to the establishment of nonnative backswimmers in Hawaiian streams and other aquatic habitat, the presence of backswimmers in these habitats, the documented predation of backswimmers on the naiads of other damselfly species, and the concurrent decline of damselfly observations in some areas suggest that these nonnative aquatic insects may have played a role in the decline of some damselfly populations, including those of the Pacific Hawaiian damselfly.

We consider predation by nonnative backswimmers to pose a significant and immediate threat to the Pacific Hawaiian damselfly, because this species has an aquatic naiad life stage. In addition, the presence of these predators in damselfly aquatic habitat causes naiads to reduce foraging, which in turn reduces their growth, development, and survival. Backswimmers are reported on all of the main Hawaiian Islands except Kahoolawe. Without elimination or control of nonnative backswimmers, we expect this threat to continue or increase over time.

Predation by Nonnative Fish

Predation by nonnative fish is a significant threat to Hawaiian damselfly species with aquatic life stages, such as the Pacific Hawaiian damselfly. The aquatic naiads tend to rest and feed near or on the surface of the water, or on rocks where they are exposed and vulnerable to predation by nonnative fish. Hawaii has only five native freshwater fish species, comprised of gobies (Gobiidae) and sleepers (Eleotridae), that occur on all of the major islands. Because these native fish are benthic (bottom) feeders (Kido *et al.* 1993, pp. 43-44; Ego 1956, p. 24; Englund 1999, pp. 236-237), Hawaii's stream-dwelling damselfly species probably experienced limited natural predation pressure due to their avoidance of benthic areas in preference for shallow side channels, sidepools, and higher velocity riffles and seeps (Englund 1999, pp. 236-237). While fish predation has been an important factor in the evolution of behavior in damselfly naiads in continental systems (Johnson 1991, pp. 8), it is speculated that Hawaii's stream-dwelling damselflies adapted behaviors to avoid the benthic feeding habits of native fish species. Additionally, some species of damselflies, including some of the native Hawaiian species, are not adapted to cohabitate with some fish species, and are found only in bodies of water without fish (Henrikson 1988, p. 179; McPeek 1990a, p. 83). The naiads of the aquatic Pacific Hawaiian damselfly tend to occupy more exposed positions and engage in conspicuous foraging behavior, thereby increasing their susceptibility to fish predation (Englund 1999, p. 232), unlike damselflies that coevolved with predaceous fish (Macan 1977, p. 48; McPeek 1990b, p. 1,714). In laboratory studies, Englund (1999, p. 232) found that naiads of the orangeblack Hawaiian damselfly and the Pacific Hawaiian damselfly invariably were eaten due to their behavior of swimming to the water surface when exposed to two nonnative freshwater fish. In the same study, naiads of nonnative damselfly species avoided predation by the same fish species by remaining still and avoiding surface waters (Englund 1999, p. 232).

Over 70 species of nonnative fish have been introduced into Hawaiian freshwater habitats (Devick 1991, p. 190; Englund 1999, p. 226; Staples and Cowie 2001, p. 32; Brasher 2003, p. 1,054; Englund 2004, p.27; Englund *et al.* 2007, p. 232); at least 53 species are now established in the freshwater habitats of Hawaii (Freshwater Fishes of Hawaii 2008, p. 1). The initial introduction of nonnative fish to Hawaii began with the release of food stock species by Asian immigrants at the turn of the 20th century; however, the impact of these first introductions to Hawaiian damselflies cannot be assessed because they predated the initial collection of damselflies in Hawaii (Perkins 1899, pp. 64-76).

In 1905, three species of fish within the Poeciliidae family, including the mosquito fish (*Gambusia affinis*) and the sailfin molly (*Poecilia latipinna*), were introduced for biological control of mosquitoes (Van Dine 1907, p. 9; Englund 1999, p. 225; Brasher 2003, p. 1054). In 1922, several additional species were introduced for mosquito control, including the green swordtail (*Xiphophorus helleri*), the moonfish (*Xiphophorus maculatus*), and the guppy (*Poecilia reticulata*). By 1935, some Oahu damselfly species, including the orangeblack Hawaiian damselfly, were becoming less common, and fish introduced for mosquito control were the suspected cause of their decline (Williams 1936, p. 313; Zimmerman 1948b, p. 341). The literature clearly indicates that the extirpation of the Pacific Hawaiian damselfly from the majority of its historical habitat sites on the main Hawaiian Islands is the result of predation by nonnative fish (Moore and Gagne 1982, p. 4; Liebherr and Polhemus 1997, p. 502; Englund 1999, pp. 235-237; Brasher 2003, p. 1,055; Englund *et al.* 2007, p. 215; Polhemus 2007, pp. 238-239). From 1946 through 1961, several additional nonnative fish were introduced for the purpose of controlling nonnative aquatic plants, and for angling (Brasher 2003, p. 1,054). In the early 1980s, several additional species of nonnative fish began appearing in stream systems, likely originating from the aquarium fish trade (Devick 1991, p. 189; Brasher 2003, p. 1,054). By 1990, there were an additional 14 species of nonnative fish established in waters on Hawaii, Maui, and Molokai. By 2008, there were at least 17 nonnative freshwater fish established on one or more of these islands, including several aggressive predators and habitat-altering species such as the channel catfish (*Ictalurus punctatus*) and cichlids (*Tilapia* sp.) (Devick 1991, pp. 191-192; FishBase 2008).

The Pacific Hawaiian damselfly is currently found only in portions of stream systems without nonnative fish (Liebherr and Polhemus 1997, pp. 493-494; Englund 1999, p. 228; Englund 2004, p. 27; Englund *et al.* 2007, p. 215). There is a strong correlation between

the absence of nonnative fish species and the presence of Hawaiian damselflies in streams on all of the main Hawaiian Islands (Englund 1999, p. 225; Englund *et al.* 2007, p. 215), suggesting that the damselflies cannot coexist with nonnative fish. The distribution of some Hawaiian damselfly species is now reduced to stream reaches less than 312 ft (95 m) in length where invasive fish species do not occur (Englund 1999, p. 229; Englund 2004, p. 27). In 2007, a Statewide survey including 15 streams on the islands of Hawaii, Maui, and Molokai found the flying earwig Hawaiian damselfly was not observed in streams where the introduced Mexican molly (*Poecilia mexicana*) was present (Englund *et al.* 2007, pp. 214-216, 228). On Oahu, researchers found that the Oahu-endemic Hawaiian damselflies only occupied habitat sites without nonnative fish. For two of these species, a geologic or manmade barrier (e.g., waterfalls, steep gradient, dry stream midreaches, or constructed diversions) appears to prevent access by the nonnative fish species. For this reason, researchers have recommended that geologically isolated sites inaccessible to nonnative fishes, such as isolated anchialine ponds, high-gradient streams interrupted by manmade diversions, and streams entering the coast as waterfalls, be used as restoration sites for damselflies on all of the Hawaiian Islands (Englund 2004, p. 27).

Of the two damselfly species considered in this final rule, the aquatic Pacific Hawaiian damselfly appears to have had the greatest range contraction due to predation by nonnative fish (Englund 1999, p. 235; Polhemus 2007, p. 234, 238-240). Once found on all of the main Hawaiian Islands, it is now found only on Molokai, Maui, and one stream on the island of Hawaii below 2,000 ft (600 m) in elevation; all are in stream reaches free of nonnative fish. The Pacific Hawaiian damselfly was extirpated from Oahu by 1910 (Liebherr and Polhemus 1997, p. 502), although Englund (1999, p. 235) found that Oahu still has abundant and otherwise suitable lowland and coastal water habitat to support this species. However, this aquatic habitat is infested with nonnative fish, with some nonnative species occurring up to 1,300-ft (400-m) elevation. In contrast, Englund (1999, p. 236) found that even at sea level, artificial wetlands (resulting from taro cultivation) on the island of Molokai can support populations of the Pacific Hawaiian damselfly because nonnative fish are absent.

Even the geographically isolated stream headwaters and other aquatic habitats where the Pacific Hawaiian damselfly remains extant are not secure from the threat of predation by introduced fish species. There are many documented cases of people moving nonnative fish from one area to another (Brock 1995, pp. 3-4; Englund 1999, p. 237). Once nonnative fish species are introduced to aquatic habitats previously free of nonnative fish, they often become permanently established (Englund and Filbert 1999, p. 151; Englund 1999, pp. 232-233; Englund *et al.* 2007). An example of facilitated fish movement occurred in 2000, when an uninformed maintenance worker introduced *Tilapia* sp. into pools located on the grounds of Tripler Hospital that were maintained for the benefit of the remaining Oahu population of the orangeblack Hawaiian damselfly (Englund 2000).

The continued introduction and establishment of new species of predatory nonnative fish in Hawaiian waters, and the possible movement of these nonnative species to new streams and other aquatic habitat, is an immediate and significant threat to the survival of the aquatic Pacific Hawaiian damselfly. Unless nonnative predatory fish are eradicated or effectively controlled in the habitats utilized by the Pacific Hawaiian damselfly, we have no reason to believe that there will be any significant reduction in this threat at any time in the near future. The flying earwig Hawaiian damselfly is not known to be threatened by predation from nonnative fish species, due to the apparent absence of the larval stage within stream habitats.

Predation by Introduced Frogs and Toads

Currently, there are three species of introduced aquatic amphibians known in the Hawaiian Islands: The North American bullfrog (*Rana catesbeiana*), the cane toad (*Bufo marinus*), and the Japanese wrinkled frog (*Rana rugosa*). The bullfrog is native to the eastern United States and the Great Plains region (Moyle 1973, p. 18; Bury and Whelan 1985 in Earlham College 2002, p. 10), and was first introduced into Hawaii in 1899 (Bryan 1931, p. 63) to help control insects, specifically the nonnative Japanese beetle (*Popillia japonica*), a significant pest of ornamental plants (Bryan 1931, p. 62). Bullfrogs were first released and quickly became established in the Hilo region on the island of Hawaii (Bryan 1931, p. 63). Bullfrogs have demonstrated great success in establishing new populations wherever they have been introduced (Moyle 1973, p. 19), and now occur on the islands of Hawaii, Kauai, Lanai, Maui, Molokai, and Oahu (U.S. Geological Survey 2008b, p. 8). This species is flexible in both habitat and food requirements (Bury and Whelan 1985 in Earlham College 2002, p. 11), and can utilize any water source within its temperature range (60 to 75 degrees Fahrenheit (°F)) (16 to 24 degrees Celsius (°C)) (DesertUSA 2008). Introduced to areas outside its native range, the bullfrog's primary impact is typically the elimination of native frog species (Moyle 1973, p. 21). In Hawaii, where there are no native frogs, the bullfrog has not been definitively implicated in the extirpation of any particular native aquatic invertebrate species, but Englund *et al.* (2007, pp. 215, 219) found a strong correlation between the presence of bullfrogs and the absence of Hawaiian damselflies in their 2006 study of streams on all of the main Hawaiian Islands. As the bullfrog prefers habitats with dense vegetation and relatively calm water (Moyle 1973, p. 19; Bury and Whelan 1985 in Earlham College 2002, p. 9), it is likely of particular threat to the Pacific Hawaiian damselfly because this species also prefers calm water habitat that is surrounded by dense vegetation. Capable of breeding within small pools of water, bullfrogs are also a potential threat to the flying earwig Hawaiian damselfly within its uluhe-covered, steep, riparian, and moist talus-slope habitat on Maui.

Because the effects of possible predation by the cane toad and the Japanese wrinkled frog on the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly are unknown at this time, the magnitude or significance of this potential threat cannot be determined.

We consider predation by bullfrogs to pose a significant and immediate threat to the Pacific Hawaiian damselfly, since Englund *et al.* (2007, pp. 215, 219) found a strong correlation between the presence of predatory nonnative bullfrogs and the absence of Hawaiian damselflies, and the preferred habitat of the bullfrog overlaps with that of the Pacific Hawaiian damselfly. Within its riparian habitat, the flying earwig Hawaiian damselfly may also be threatened by the bullfrog, which is capable of breeding within small pools of water. In the absence of the elimination or control of nonnative bullfrogs, we expect that this threat will continue or increase in the future.

Summary of Factor C

Predation by nonnative animal species (ants, backswimmers, fish, and bullfrogs) poses an immediate and significant threat to the Pacific and flying earwig Hawaiian damselflies

throughout their ranges for the following reasons:

- Damselfly naiads are vulnerable to predation by ants, and the ranges of both the Pacific and flying earwig Hawaiian damselflies overlap that of particularly aggressive, nonnative, predatory ant species that currently occur from sea level to 2,000 ft (610 m) elevation on all of the main Hawaiian Islands. We consider both the Pacific and flying earwig Hawaiian damselflies to be threatened by predation by these nonnative ants.
- Nonnative backswimmers prey on damselfly naiads in streams and other aquatic habitat, and are considered a threat to the Pacific Hawaiian damselfly since this species has an aquatic naiad life stage. In addition, the presence of backswimmers inhibits the foraging behavior of damselfly naiads, with negative consequences for development and survival. Backswimmers are reported on all of the main Hawaiian Islands except Kahoolawe.
- The absence of Hawaiian damselflies, including the aquatic Pacific Hawaiian damselfly, in streams and other aquatic habitat on the main Hawaiian Islands, is strongly correlated with the presence of predatory nonnative fish as documented in numerous observations and reports (Englund 1999, p. 237; Englund 2004, p. 27; Englund *et al.* 2007, p. 215), thereby suggesting that nonnative predatory fishes eliminated native Hawaiian damselflies from these aquatic habitats. There are over 51 species of nonnative fishes established in freshwater habitats on the Hawaiian Islands from sea level to over 3,800-ft (1,152-m) elevation (Devick 1991, p. 190; Staples and Cowie 2001, p. 32; Brasher 2003, p. 1054; Englund 1999, p. 226; Englund and Polhemus 2001; Englund 2004, p. 27; Englund *et al.* 2007, p. 232). Predation by nonnative fishes is considered to pose a significant and immediate threat to the Pacific Hawaiian damselfly.
- Englund *et al.* (2007, pp. 215, 219) found a strong correlation between the presence of nonnative bullfrogs and the absence of Hawaiian damselflies. Bullfrogs are reported on all of the main Hawaiian Islands, except Kahoolawe and Niihau. The Pacific Hawaiian damselfly is likely threatened by bullfrogs, due to their shared preference for similar habitat, and the flying earwig Hawaiian damselfly may also be threatened within its riparian habitat by the bullfrog, which is capable of breeding within small pools of water.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

Inadequate Habitat Protection

Currently, there are no Federal, State, or local laws, treaties, or regulations that specifically conserve or protect the flying earwig Hawaiian damselfly or the Pacific Hawaiian damselfly from the threats described in this final rule. The State of Hawaii considers all natural flowing surface water (streams, springs, and seeps) as State property (Hawaii Revised Statutes 174c 1987), and the Hawaii Department of Land and Natural Resources (DLNR), Division of Aquatic Resources has management responsibility for the aquatic organisms in these waters (Hawaii Revised Statutes Annotated, 1988, Title 12; 1992 Cumulative Supplement). Thus, damselfly populations associated with streams, seeps, and springs are under the jurisdiction of the State of Hawaii, regardless of the ownership of the property across which the stream flows. This includes all populations of the Pacific Hawaiian damselfly and the flying earwig Hawaiian damselfly.

The State of Hawaii manages the use of surface and groundwater resources through the Commission on Water Resource Management (Water Commission), as mandated by the 1987 State Water Code (State Water Code, Hawaii Revised Statutes Chapter 174C-71, 174C-81-87, and 174C-9195, and Administrative Rules of the State Water Code, Title 13, Chapters 168 and 169). In the State Water Code, there are no formal requirements that project proponents or the Water Commission protect the habitats of fish and wildlife prior to issuance of a permit to modify surface or groundwater resources.

As noted above in *Factor A*, the Water Commission is now more cognizant of the effects that groundwater removal has on streams via injudicious placement of wells. The Commission routinely reviews new permit applications for wells (Hardy 2009, p. 1). All requests for new wells require a drilling permit, and, in some cases, a use permit is additionally required, depending upon the intended allocation and anticipated amount of water to be pumped from the well. Water Management Areas have been designated over much of Oahu and in some areas on other neighboring islands. Within these areas, a use permit for a new well is also required, which automatically triggers a greater review of the potential impacts. Any request for a permit to drill a well within proximity of streams or dike rock located at the headwaters of streams automatically triggers additional review (Hardy 2009). Permits to drill wells near streams or within dike complexes are now unlikely to be granted because a new well would require the amendment of in-stream flow standards for the impacted stream. However, such amendments are sometimes approved. One example is the long-contested case involving the Waiahole Ditch on the island of Oahu (Hawaii Department of Agriculture 2002, p. 3). In that case, the Commission supports the removal of several million gallons of water daily from windward Oahu streams (Hawaii Department of Agriculture 2002). Although a regulatory process is in place that can potentially address the effects of new requests for groundwater removal on streams, this process includes provisions for amendments that would result in adverse effects to groundwater that supports streamside habitat for the Pacific Hawaiian damselfly, and potentially for the flying earwig Hawaiian damselfly.

The maintenance of instream flow, which is needed to protect the habitat of damselflies and other aquatic wildlife, is regulated by the establishment of standards on a stream-by-stream basis (State Water Code, Hawaii Revised Statutes Chapter 174C-71, and Administrative Rules of the State Water Code, Title 13, Chapter 169). Currently, the interim instream flow standards represent the existing flow conditions in streams in the State (as of June 15, 1988, for Molokai, Hawaii, Kauai and east Maui; and October 19, 1988, for west Maui and leeward Oahu) (Administrative Rules of the State Water Code, Title 13, Chapter 169-44-49). However, the State Water Code does not provide permanent or minimal instream flow standards for the protection of aquatic wildlife. Instead, modification of instream flow standards and stream channels can be undertaken at any time by the Water Commission or via public petitions to revise flow standards or modify stream channels in a specified stream (Administrative Rules of the State Water Code, Title 13, Chapter 169-36). Additionally, the Water Commission must consider economic benefits gained from out-of-stream water uses, but is not required to balance these benefits against instream benefits or impacts to aquatic fish and wildlife. Consequently, any stabilization of stream flow for the protection of any native Hawaiian damselfly species habitat is subject to modification at a future date.

The natural value of Hawaii's stream systems has been recognized under the State of Hawaii Instream Use Protection Program (Administrative Rules of the State Water Code, Title 13, Chapter 169-20(2)). In the Hawaii Stream Assessment Report (1990), prepared in coordination with the National Park Service, the State Water Commission identified high-quality rivers or streams, or portions of rivers or streams, that may be placed within the Federal Wild and Scenic River system. This report recommended that streams meeting certain criteria be protected from further development. However, there is no formal or institutional mechanism within the State's Water Code to designate and set aside these streams, or to identify and protect stream habitat for Hawaiian damselflies. Furthermore, the setting of instream flow standards sufficient to conserve Hawaiian damselflies is currently not a condition that would be considered or included in a Hawaii Department of Agriculture individual permit (DLNR, Commission on Water Resource Management 2006, p. 2).

Existing Federal regulatory mechanisms that may protect Hawaiian damselflies and their habitat are also inadequate. The Federal Energy Regulatory Commission (FERC) has very limited jurisdiction in Hawaii. Hawaii's streams are isolated on individual islands and run quickly down steep volcanic slopes. There are no interstate rivers in Hawaii, few if any streams crossing Federal land, and no Federal dams. Many of Hawaii's streams are generally intermittent, or if perennial, not navigable. Thus, licensing of hydroelectric projects in Hawaii generally does not come under the purview of FERC, although hydropower developers in Hawaii may voluntarily seek licensing under FERC.

In contrast, the U.S. Army Corps of Engineers (Corps) has some regulatory control over modifications of freshwater streams in the United States, yet may assert discretion relative to jurisdictional determinations depending on the surface water connection of the stream to a tangible water of the United States. If the Corps finds the stream to be jurisdictional, certain activities such as road crossings for streams and bank stabilization can be subject to a streamlined permitting process (33 CFR 330). This process, called the nationwide permits program, can involve only limited public review if impacts are anticipated to be minimal, both individually and cumulatively.

The Service and the Hawaii DLNR have 15 days to provide substantive site-specific comments prior to the issuance of a nationwide permit. Given the complexity of the impacts on Hawaiian damselflies from stream modifications and surface water diversions, the remoteness of project sites, and the types of studies necessary to determine project impacts and mitigation, this limited comment period does not allow time for an adequate assessment of impacts. This regulation is inadequate to protect the damselflies because the Corps is under no obligation to modify the project based upon comments received.

However, if the stream is jurisdictional and impacts are expected to exceed the thresholds for a nationwide permit, the Corps can issue individual permits under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq*.). These permits are subject to public review, and must comply with the Environmental Protection Agency's 404(b)(1) guidelines and public comment requirements under the Clean Water Act. Compensatory mitigation may also be required to offset lost stream functions. However, in issuing these permits, the Corps does not establish instream flow standards as a matter of policy. The Corps normally considers that the public interest for instream flow is represented by the State water allocation rights or preferences (U.S. Army Corp of Engineers' Regulatory Guidance Letter No 85-6), and project alternatives that supersede, abrogate, or otherwise impair the State water quantity allocations are not normally addressed as alternatives during permit review.

In cases where the Corps district engineer does propose to impose instream flow standards on an individual permit, this flow standard must reflect a substantial national interest. Additionally, if this instream flow standard is in conflict with a State water quantity allocation, then it must be reviewed and approved by the Office of the Chief Engineer in Washington, D.C. (Regulatory Guidance Letter No 85-6).

One population of the Pacific Hawaiian damselfly occurs in Palikea Stream on Maui, which flows through Haleakala National Park. On Molokai, populations of this damselfly species occur at the mouth of Pelekunu Stream, which flows through a preserve managed by The Nature Conservancy, and in lower Waikolu Stream, which flows through Kalaupapa National Historic Park. However, the landowners do not own the water rights to any of the streams, and thus cannot fully manage the conservation of any of these damselfly populations.

Because there are currently no Federal, State, or local laws or treaties or regulations that adequately conserve or protect habitat of the flying earwig Hawaiian damselfly or the Pacific Hawaiian damselfly from the threats described in this final rule, and the regulations currently in place are inadequate to maintain stream and riparian habitats and protect the two damselfly species from stream modifications and surface water diversions, all of these threats remain immediate and significant. The habitat of both species continues to be reduced, degraded, and altered by past and present manmade alterations to streams and riparian zones.

Inadequate Protection from Introduction of Nonnative Species

As discussed above (see *Factor C. Disease or Predation*), predation by nonnative species (fish, insects, and bullfrogs) is one of the most significant threats to the survival of the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly.

Based on historical and current rates of aquatic species introductions (both purposeful and accidental), existing State and Federal regulatory mechanisms are not adequately preventing the spread of nonnative species between islands and watersheds in Hawaii. The Hawaii Department of Agriculture has administrative rules in place that address importation of nonnative species and establish a permit process for such activities (Hawaii Administrative Rules sec. 4-71). The Division of Aquatic Resources within the Hawaii Department of Land and Natural Resources (HDLNR) has authority to seize, confiscate, or destroy as a public nuisance, any fish or other aquatic life found in any waters of the State and whose importation is prohibited or restricted under rules of the Department of Agriculture (Section 187A-2(4 H.R.S. sec. 187A-6.5)). Although State and Federal regulations are now firmly in place to prevent the unauthorized entry of nonnative aquatic species into the State of Hawaii, movement of species between islands and from one watershed to the next remains problematic even while prohibited (HDAR 2003, pp. 2/12 – 2/14). For example, while unauthorized movement of an aquatic species from one watershed to the next may be prohibited, there simply is not enough government funding to adequately enforce such regulation or to provide for sufficient inspection services and monitoring, although this priority need is recognized (Cravalho 2009, p. 1). Furthermore, due to the complexity of the pathways of invasion by aquatic species (i.e., intentional, inadvertent,

and by forces of nature), many components contributing to the problem may be better addressed through greater public outreach and education (Montgomery 2009, p. 1).

On the basis of the above information, we find that existing regulatory mechanisms do not adequately protect the flying earwig Hawaiian damselfly or the Pacific Hawaiian damselfly from the threat of established nonnative species (particularly fish and insect species) spreading between islands and watersheds, where they may prey upon or directly compete with the two damselfly species for food and space. Because current Federal, State, and local laws and treaties and regulations are inadequate to prevent the spread of nonnative aquatic animals between islands and watersheds, the impacts from these introduced threats remain immediate and significant. From habitat-altering, nonnative plant species to predation or competition caused by introduced frogs, nonnative fish, and insect species, the Pacific Hawaiian damselfly and the flying earwig Hawaiian damselfly are immediately and significantly threatened by former and new plant and animal introductions within the damselflies' remaining habitat.

Summary of Factor D

The aquatic habitat of the flying earwig and the Pacific Hawaiian damselflies is under the jurisdiction of the State of Hawaii, which also has management responsibility for aquatic organisms. However, the State Water Code has no regulatory mechanism in place to protect these species or their habitat. The State Water Code does not currently provide for permanent or minimum instream flow standards for the protection of aquatic ecosystems upon which these damselfly species depend, and does not contain a regulatory mechanism for identifying and protecting damselfly habitat under a Wild and Scenic River designation.

To date, administration of the Clean Water Act permitting program by the U.S. Army Corps of Engineers has not provided substantive protection of damselfly habitat, including any requirements for retention of adequate instream flows.

Existing State and Federal regulatory mechanisms are not adequately regulating the spread of nonnative animal species between islands and watersheds. Predation by nonnative animal species poses a major ongoing threat to the flying earwig and the Pacific Hawaiian damselflies. Because existing regulatory mechanisms are inadequate to maintain aquatic habitat for the damselflies and to regulate the spread of nonnative species, the inadequacy of existing regulatory mechanisms is considered to be a significant and immediate threat.

Factor E. Other Natural or Manmade Factors Affecting the Species' Continued Existence

Small Numbers of Populations and Individuals

Species that are endemic to single islands or known from few, widely dispersed locations are inherently more vulnerable to extinction than widespread species because of the higher risks from genetic bottlenecks, random demographic fluctuations, climate change, and localized catastrophes such as hurricanes, landslides, and drought (Lande 1988, p. 1,455; Mangel and Tier 1994, p. 607; Pimm *et al.* 1988, p. 757). These problems are further magnified when populations are few and restricted to a limited geographic area, and the number of individuals is very small. Populations with these characteristics face an increased likelihood of stochastic extinction due to changes in demography, the environment, genetics, or other factors, in a process described as an "extinction vortex" by Gilpin and Soul´e (1986, pp. 24-25). Small, isolated populations often exhibit a reduced level of genetic variability or genetic depression due to inbreeding, which diminishes the species' capacity to adapt and respond to environmental changes, thereby lessening the probability of long-term persistence (Soul´e 1987, pp. 4-7). The problems associated with small population size and vulnerability to random demographic fluctuations or natural catastrophes are further magnified by synergistic interactions with other threats, such as those discussed above (Factors A–C).

Historically, the two damselfly species were more widespread, present on several Hawaiian islands. An important benefit of this greater historical range, especially the fact they were on several islands from which they are now extirpated, resulted in an advantage of redundancy: Additional populations separated by some distance likely allowed some populations to be spared the impacts of localized or more discrete catastrophic events, such as narrow-track hurricanes or mud slides. However, this advantage of redundancy has been lost with the great reduction in the damselflies' ranges.

Jordan *et al.* (2007, p. 247) showed in their genetic and comparative phylogeography analysis (study of historical processes responsible for genetic divergence within a species) of four *Megalagrion* species that the Pacific Hawaiian damselfly may be more susceptible to problems linked to low genetic diversity compared to other Hawaiian damselfly species. Both Maui and Molokai populations of this species were analyzed, and results suggested that the Pacific Hawaiian damselfly may not disperse well across both land and water, which may have led to the low genetic diversity observed in the two populations sampled. The authors proposed that populations of the Pacific Hawaiian damselfly be monitored and managed to help understand the conservation needs of this species and the threat of population bottlenecks (Jordan *et al.* 2007, p. 258). This study did not include an analysis of the flying earwig Hawaiian damselfly. However, given that this species may now be reduced to a single population, the potential loss of genetic diversity and threat of inbreeding depression is a concern for the flying earwig Hawaiian damselfly as well.

The small number of remaining populations of the flying earwig Hawaiian damselfly (now possibly reduced to a single remaining population) puts this species at significant risk of extinction from stochastic events, such as hurricanes, landslides, or prolonged drought (Jones *et al.* 1984, p. 209). For example, Polhemus (1993, p. 87) documented the extirpation of a related damselfly species, *Megalagrion vagabundum*, from the entire Hanakapiai Stream system on Kauai as a result of the impacts from Hurricane Iniki in 1992. Such stochastic events thus pose the threat of immediate extinction of a species with a very small and geographically restricted distribution, as in the case of the flying earwig Hawaiian damselfly.

Summary of Factor E

The threat to the flying earwig and Pacific Hawaiian damselflies from limited numbers of populations and individuals is significant and immediate for the following reasons:

- Each of these species is subject to potentially reduced reproductive vigor due to inbreeding depression, particularly the flying earwig Hawaiian damselfly, which is now apparently restricted to one population;
- Each of these species is subject to reduced levels of genetic variability that may diminish their capacity to adapt and respond to environmental changes, thereby lessening the probability of their long-term persistence;

- The potential benefits of redundancy resulting from the wider historical distribution of the species, in which some populations might survive stochastic events that impact other populations of the damselflies, has been lost as a result of the extreme reduction in the ranges of the two species;
- As there may be only one remaining population of the flying earwig Hawaiian damselfly that occurs in a relatively restricted geographic location, a single catastrophic event, such as a hurricane or landslide, could result in the extinction of the species. Likewise, the Pacific Hawaiian damselfly, with several small, widely dispersed populations, would be vulnerable to the extirpation of remaining populations; and
- Species with few populations and a small number of individuals, such as the Pacific Hawaiian damselfly and flying earwig Hawaiian damselfly, are less resilient to threats that might otherwise have a relatively minor impact on a larger population. For example, the reduced availability of breeding habitat or an increase in predation of naiads, which might be absorbed in a relatively large population, could result in a significant decrease in survivorship or reproduction of a relatively small, isolated population. The small population size of these two species thus magnifies the severity of the impact of the other threats discussed in this final rule.

Determination

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly. We find that both of these species face immediate and significant threats throughout their ranges:

- Both the Pacific Hawaiian damselfly and the flying earwig Hawaiian damselfly face threats from past, present, and potential future destruction, modification, and curtailment of their habitats, primarily from: Agriculture and urban development; stream diversion, well-drilling, channelization, and dewatering; feral pigs and nonnative plants; and from stochastic events like hurricanes, landslides, and drought. The changing environmental conditions that may result from climate change (particularly rising temperatures) are also likely to threaten these two damselfly species (compounded because of the two species' small population sizes and limited distributions), although currently there is limited information on the exact nature of these impacts (see discussion under Factor A).
- The only known population of the flying earwig Hawaiian damselfly is immediately and significantly threatened by potential recreational collection (see Factor B).
- Both the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly are subject to an immediate and significant threat of predation by nonnative insects (ants) and bullfrogs. The Pacific Hawaiian damselfly is also similarly threatened by backswimmers and nonnative fish (see Factor C).
- The inadequacy of existing regulatory mechanisms (e.g., inadequate protection of stream habitat and inadequate protection from the introduction of nonnative species) poses a threat to both species of Hawaiian damselfly, as discussed under Factor D above.
- Both of these species face an immediate and significant threat from extinction due to factors associated with small numbers of populations and individuals as discussed under Factor E above.

All of the above threats are exacerbated by the inherent vulnerability of the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly to extinction from stochastic events at any time because of their endemism (indigenousness), small numbers of individuals and populations, and restricted habitats.

The Act defines an endangered species as any species that is "in danger of extinction throughout all or a significant portion of its range" and a threatened species as any species "that is likely to become endangered throughout all or a significant portion of its range within the foreseeable future." We find that each of these two species endemic to Hawaii is presently in danger of extinction throughout its entire range, based on the immediacy, severity, and scope of the threats described above. Therefore, on the basis of the best available scientific and commercial information, we are listing the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly as endangered in accordance with sections 3(6) and 4(a)(1) of the Act.

Under the Act and our implementing regulations, a species may warrant listing if it is endangered or threatened throughout all or a significant portion of its range. Each of the two endemic damselfly species designated as endangered in this final rule is highly restricted in its range, and the threats to its survival occur throughout its range and are not restricted to any particular significant portion of that range. Therefore, we assessed the status of each species throughout its entire range. Accordingly, our assessment and final determination apply to each species throughout its entire range.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain activities. Recognition through listing results in public awareness and conservation by Federal, State, Tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and requires that recovery actions be carried out for all listed species. The protection required by Federal agencies, and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Subsection 4(f) of the Act requires the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed, preparation of a draft and final recovery plan, and revisions to the plan as significant new information becomes available. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. The recovery plan identifies site-specific management actions that will achieve recovery of the species, measurable criteria that determine when a species may be downlisted or delisted,

and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (comprised of species experts, Federal and State agencies, nongovernment organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available from our website (*http://www.fws.gov/endangered*), or from our Pacific Islands Fish and Wildlife Office (see **ADDRESSES**).

Implementation of recovery actions generally benefits from the participation of a broad range of partners, including other Federal agencies, States, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (e.g., restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private and State lands.

Upon listing, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, under section 6 of the Act, the State of Hawaii is eligible for Federal funds to implement management actions that promote the protection and recovery of the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants*.

Please let us know if you are interested in participating in recovery efforts for the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly. Additionally, we invite you to submit any new information on these species whenever it becomes available and any information you may have for recovery planning purposes (see **ADDRESSES**).

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of a listed species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require consultation as described in the preceding paragraph include, but are not limited to: Army Corps of Engineers involvement in projects, such as the construction of roads, bridges, and dredging projects, subject to section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) and section 10 of the Rivers and Harbors Act of 1899 (33 U.S.C. 401 *et seq.*); U.S. Environmental Protection Agency–authorized discharges under the National Pollutant Discharge Elimination System (NPDES); U.S. Department of Agriculture involvement in the release or permitting of the release of biological control agents under the Federal Plant Pest Act (7 U.S.C. 150aa-150jj); military training and related activity carried out by the U.S. Department of Defense; and projects by the Natural Resources Conservation Service, National Park Service, U.S. Fish and Wildlife Service, Federal Highways Administration, and the U.S. Department of Housing and Urban Development.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to all endangered and threatened wildlife. The prohibitions of section 9(a)(2) of the Act, codified at 50 CFR 17.21 for endangered wildlife, in part, make it illegal for any person subject to the jurisdiction of the United States to take (includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt any of these), import, export, ship in interstate commerce in the course of a commercial activity, or sell or offer for sale in interstate or foreign commerce any listed species. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to our agents and State conservation agencies.

We may issue permits to carry out otherwise-prohibited activities involving endangered and threatened wildlife species under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22 for endangered species. A permit must be issued for the following purposes: For scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of species proposed for listing. The following activities could potentially result in a violation of section 9 of the Act; this list is not comprehensive:

(1) Unauthorized collecting, handling, possessing, selling, delivering, carrying, or transporting of the species, including import or export across State lines and international boundaries, except for properly documented antique specimens of these taxa at least 100 years old, as defined by section 10(h)(1) of the Act;

(2) Introduction of nonnative species that compete with or prey upon the two damselflies, such as the introduction of competing nonnative insects or predatory fish to the State of Hawaii;

(3) The unauthorized release of biological control agents that attack any life stage of these species;

(4) Unauthorized modification of the channel or water flow of any stream or removal or destruction of emergent aquatic vegetation in any body of water in which the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly are known to occur; and

(5) Unauthorized discharge of chemicals or fill material into any waters in which the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly are known to occur.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Pacific Islands Fish and Wildlife Office (see **ADDRESSES**). Requests for copies of the regulations concerning listed animals and general inquiries regarding prohibitions and permits may be addressed to the U.S. Fish and Wildlife Service, Endangered Species Permits, 911 N.E. 11th Avenue, Portland, OR 97232-4181 (telephone 503-231-2063; facsimile 503-231-6243).

Upon listing under the Act, the State of Hawaii's Endangered Species Act (HRS, Sect. 195D–4(a)) is automatically invoked, which would also prohibit take of these species and encourage conservation by State government agencies. Further, the State may enter into agreements with Federal agencies

to administer and manage any area required for the conservation, management, enhancement, or protection of endangered species (HRS, Sect. 195D–5(c)). Funds for these activities could be made available under section 6 of the Act (Cooperation with the States). Thus, the Federal protection afforded to these species by listing them as endangered species will be reinforced and supplemented by protection under State law.

Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the provisions of section 4 of the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species; and

(b) Which may require special management considerations or protections; and

(2) Specific areas outside the geographical area occupied by a species at the time it is listed in accordance with the provisions of section 4 of the Act, upon a determination by the Secretary of the Interior that such areas are essential for the conservation of the species.

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided under the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the prohibition against Federal agencies carrying out, funding, or authorizing the destruction or adverse modification of critical habitat. Section 7(a)(2) of the Act requires consultation on Federal actions that may affect critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public access to private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by the landowner. Where a landowner seeks or requests Federal agency funding or authorization that may affect a listed species or critical habitat, the consultation requirements of section 7(a)(2) of the Act would apply, but even in the event of a destruction or adverse modification finding, the Federal action agency's and landowner's obligation is not to restore or recover the species, but to implement reasonable and prudent alternatives to avoid destruction or adverse modification of the critical habitat.

For inclusion in a critical habitat designation, the habitat within the geographical area occupied by the species at the time of listing must contain the physical and biological features essential to the conservation of the species, and be included only if those features may require special management considerations or protection. Critical habitat designations identify, to the extent known using the best scientific data available, habitat areas that provide essential life cycle needs of the species (i.e., areas on which are found the primary constituent elements (PCEs) laid out in the appropriate quantity and spatial arrangement for the conservation of the species). Under the Act, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed only when we determine that those areas are essential for the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific and commercial data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106-554; H.R. 5658)), and our associated Information Quality Guidelines issued by the Service, provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information developed during the listing process for the species. Additional information sources may include the recovery plan for the species, if available; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; or other unpublished materials and expert opinion or personal knowledge.

Habitat is often dynamic, and species may move from one area to another over time. Furthermore, we recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be required for recovery of the species.

Areas that are important to the conservation of the species, but are outside the critical habitat designation, will continue to be subject to conservation actions we implement under section 7(a)(1) of the Act. Areas that support populations are also subject to the regulatory protections afforded by section 9 prohibitions and the section 7(a)(2) jeopardy standard, as determined on the basis of the best available scientific information at the time of the agency action. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available at the time of these planning efforts warrants otherwise.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time a species is determined to be endangered or threatened. Our regulations (50 CFR 424.12(a)(1)) state that designation of critical habitat is not prudent when one or both of the following situations exist: (1) The species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species, or (2) such designation of

critical habitat would not be beneficial to the species.

In the absence of finding that the designation of critical habitat would increase threats to a species, if there are any benefits to a critical habitat designation, then we would determine that the designation of critical habitat is prudent. We find that the designation of critical habitat for the two damselfly species addressed in this rule will benefit them by: (1) Triggering consultation under section 7 of the Act for Federal actions where consultation would not otherwise occur because, for example, the affected area has become unoccupied by the species or the occupancy is in question; (2) focusing conservation efforts on the most essential habitat features and areas; (3) providing educational benefits about the species to State or County governments or private entities; and (4) preventing people from causing inadvertent harm to the species.

The primary regulatory effect of critical habitat is the section 7(a)(2) requirement that Federal agencies refrain from taking any action that destroys or adversely modifies critical habitat. On the island of Maui, one population of the Pacific Hawaiian damselfly occurs in a stream that flows through Haleakala National Park, and on the island of Molokai, one population of this species occurs in the lower section of a stream that flows through Kalaupapa National Historical Park. The National Park Service regulations and Federal laws protect native animals in National Parks from harassment or destruction. Nevertheless, lands that may be designated as critical habitat in the future for this species may be subject to Federal actions that trigger the section 7 consultation requirement, such as the granting of Federal monies for conservation projects or the need for Federal permits for projects, such as the construction and maintenance of aqueducts and bridges subject to section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*).

There may also be some educational or informational benefits from the designation of critical habitat. Educational benefits include the notification of landowners, land managers, and the general public of the importance of protecting the habitat of these species.

Critical habitat may play a role in protecting habitat for future reintroductions of a species as well. For example, although the flying earwig Hawaiian damselfly formerly inhabited areas that are not currently occupied by the species, if those currently unoccupied areas are determined to be essential to the survival and recovery of the species, they may be proposed for designation of critical habitat. This would alert the public that these areas are important for the future recovery of the species, as well as invoke the protection of these areas under section 7 of the Act with regard to any possible Federal actions in that area.

These aspects of critical habitat designation would potentially benefit the conservation of both the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly. Although collection has been identified as a threat to the flying earwig Hawaiian damselfly, we believe that collection poses a potential threat to this rare species regardless of the designation of critical habitat. Therefore, since we have determined that the identification of critical habitat will not increase the degree of threats to these species and because the designation may provide some measure of benefit, we find that designation of critical habitat is prudent for both the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly.

Critical Habitat Determinability

As stated above, section 4(a)(3) of the Act requires the designation of critical habitat concurrently with the species' listing "to the maximum extent prudent and determinable." Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

(i) Information sufficient to perform required analyses of the impacts of the designation is lacking, or

(ii) The biological needs of the species are not sufficiently well known to permit identification of an area as critical habitat.

When critical habitat is not determinable, the Act provides for an additional year to publish a critical habitat designation (16 U.S.C. 1533(b)(6)(C)(ii)).

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12, in determining which areas occupied by the species at the time of listing to designate as critical habitat, we consider those physical and biological features essential to the conservation of the species that may require special management considerations or protection. We consider the physical or biological features essential to the species' conservation to be the primary constituent elements laid out in the appropriate quantity and spatial arrangement for the conservation of the species. The primary constituent elements include, but are not limited to:

(1) Space for individual and population growth, and for normal behavior;

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements;

(3) Cover or shelter;

(4) Sites for breeding, reproduction, rearing (or development) of offspring; and

(5) Habitats that are protected from disturbance or are representative of the historical geographical and ecological distributions of a species.

We are currently unable to identify the physical and biological features that are considered essential to the conservation of either damselfly species, because necessary information is not available at this time. Key features of the life histories of these damselfly species, such as longevity, larval stage requirements, and fecundity, remain unknown. The aquatic and associated upland habitats where the populations of the Pacific Hawaiian damselfly are found have been modified and altered by development and agriculture; stream diversions, channelization, and dewatering; and nonnative plants. In addition, introduced ants, backswimmers, bullfrogs, and predatory nonnative fish have altered and degraded the habitat for the Pacific Hawaiian damselfly. Likewise, the uluhe-dominated, moist talus-slope habitats where populations of the flying earwig Hawaiian damselfly once occurred have been modified and altered by agriculture; stream diversions, channelization, and dewatering; and the presence of feral pigs, nonnative plants, and introduced ants and bullfrogs. Historically, both of these damselfly species were much more widespread and occurred in habitats found on several different islands. Because over a century has elapsed since these species were observed in an unaltered environment, the optimal natural conditions that provide the biological or ecological requisites of these species are not known. As described above, we can surmise that habitat degradation from a variety of factors and predation by a number of nonnative species has contributed to the decline of these species; however, we do not know the physical or biological features that are essential for either of the two damselflies addressed in this final rule. As we are unable to identify the physical and biological features essential to the conservation of these species, we are unable to identify areas that contain these features.

Although we have determined that the designation of critical habitat is

prudent for the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly, the biological needs of these species are not sufficiently well known to permit identification of the physical and biological features that may be essential for the conservation of the species, or those areas essential to the conservation of the species. Therefore, we find that critical habitat for the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly is not determinable at this time. Over the next year, we intend to continue gathering information regarding the essential life history requirements of the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly to facilitate identification of essential features and areas. We also will evaluate the needs of the flying earwig Hawaiian damselfly and the Pacific Hawaiian damselfly within the ecological context of the broader ecosystems in which they occur, similar to the approach that we recently used in our designation of critical habitat for 47 species endemic to the island of Kauai (April 13, 2010; 75 FR 18959), and will consider the utility of using this approach for these damselfly species as well.

Required Determinations

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

This rule does not contain any new collections of information that require approval by Office of Management and Budget (OMB) under the Paperwork Reduction Act. This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 *et seq.*)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted under section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A complete list of all references cited in this rule is available on the Internet at *http://www.regulations.gov* or upon request from the Field Supervisor, Pacific Islands Fish and Wildlife Office (see **ADDRESSES**).

Authors

The primary authors of this document are the staff members of the Pacific Islands Fish and Wildlife Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

■ Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as follows:

PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361-1407; 16 U.S.C. 1531-1544; 16 U.S.C. 4201-4245; Pub. L. 99-625, 100 Stat. 3500; unless otherwise noted.

■ 2. Amend § 17.11(h) by adding entries for "Damselfly, flying earwig Hawaiian" and "Damselfly, Pacific Hawaiian" in alphabetical order under Insects to the List of Endangered and Threatened Wildlife to read as follows:

§17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*		*
INSECTS							
*	*	*	*	*	*		*
Damselfly, flying earwig Hawaiian	*Megalagrion nesiotes*	U.S.A. (HI)	NA	E	271	NA	NA
Damselfly, Pacific Hawaiian	*Megalagrion pacificum*	U.S.A. (HI)	NA	E	271	NA	NA
*	*	*	*	*	*		*

* * * * *

Dated: June 11, 2010

Jeffrey L. Underwood,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2010–15237 Filed 6–23– 10; 8:45 am]

BILLING CODE 4310–55–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 100201058–0260–02]

RIN 0648–AY50

Fisheries of the Northeastern United States; 2010 Specifications for the Spiny Dogfish Fishery

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS announces specifications and management measures for the spiny dogfish fishery for the 2010 fishing year (FY) (May 1, 2010, through April 30, 2011). NMFS is implementing a spiny dogfish quota of 15 million lb (6,803.89 mt) for FY 2010, and maintaining the possession limit of 3,000 lb (1.36 mt). These measures are consistent with the Spiny Dogfish Fishery Management Plan (FMP) and based on new biological reference points announced by peer reviewers of the Transboundary Resource Assessment Committee (TRAC), which indicated the stock is rebuilt.

DATES: Effective July 26, 2010 through April 30, 2011.

ADDRESSES: Copies of supporting documents used by the Mid-Atlantic Fishery Management Council (MAFMC), including the Environmental Assessment (EA) and Regulatory Impact Review (RIR)/Initial Regulatory Flexibility Analysis (IRFA), are available from: Richard Seagraves, Acting Deputy Director, Mid–Atlantic Fishery Management Council, Room 2115, Federal Building, 300 South New Street, Dover, DE 19904–6790. The revised EA/RIR/IRFA updated after the announcement of new biological reference points is also accessible via the Internet at *http://www.nero.noaa.gov*.

NMFS prepared a Final Regulatory Flexibility Analysis (FRFA), which is contained in the Classification section of the preamble of this rule. Copies of the FRFA and the Small Entity Compliance Guide are available from the Regional Administrator, Northeast Regional Office, NMFS, 55 Great Republic Drive, Gloucester, MA 01930–2276, and are also available via the internet at *http://www.nero.nmfs.gov*.

FOR FURTHER INFORMATION CONTACT: Lindsey Feldman, Fisheries Management Specialist, phone: 978–675–2179, fax: 978–281–9135.

SUPPLEMENTARY INFORMATION:

Background

A proposed rule for this action was published in the **Federal Register** on April 2, 2010 (75 FR 16716), with public comment accepted through May 3, 2010. NMFS proposed to establish a commercial quota of 12 million lb (5,443.11 mt), the level calculated to achieve the fishing mortality rate (F) that would rebuild the stock ($F_{rebuild}$) after accounting for other sources of fishing mortality. NMFS also proposed maintaining the possession limit of 3,000 lb (1.36 mt) for FY 2010. As noted in the preamble to the proposed rule, the proposed commercial quota of 12 million lb (5,443.11 mt) was consistent with the rebuilding F level ($F_{rebuild}$ = 0.11) in existence at that time. As also noted, the Transboundary Resource Assessment Committee (TRAC) conducted a benchmark stock assessment for spiny dogfish in February 2010, and planned to re-examine biological reference points. The proposed rule explained that the FMP provides a mechanism to allow updated stock status determination criteria to be used in setting final specifications. Details about the proposed measures were included in the preamble of the proposed rule and are not repeated here.

The TRAC met in early February 2010, and determined that additional analysis would be conducted by a group of selected peer reviewers to further define biological reference points, in particular to determine the status of the spiny dogfish stock for the purposes of U.S. management.

Revised Stock Status Determination Criteria

On April 6, 2010, the group of peer reviewers selected by the TRAC accepted a newly defined biomass target of 159,288 mt, based on analysis of information in the TRAC assessment. The reviewers concluded that the updated stochastic estimate of spawning stock biomass (SSB) for 2009 (163,256 mt) exceeded the newly defined biomass target, and that estimates of SSB have been above the new biomass target since 2008, consistent with a rebuilt stock. Therefore, the spiny dogfish stock can be considered rebuilt for the purposes of U.S. management. In addition, the peer reviewers agreed on a new fishing mortality rate target (F_{target}) of 0.207 (previously 0.28), which allows 1.5 pups per recruit, and a fishing mortality rate threshold ($F_{threshold}$) of 0.325 (previously 0.39). Based on the updated stock status determination criteria, NMFS sent a letter to the Councils that the spiny dogfish stock is rebuilt.

The F_{target} of 0.207 could allow the 2010 quota to be specified as high as 21.5 million lb (9,752.24 mt). However, the Mid-Atlantic and New England Fishery Management Councils' Joint Spiny Dogfish Committee (Committee) submitted a comment on the proposed rule that supported increasing the FY 2010 commercial quota to a level that employs a constant catch management approach and avoids dramatic fluctuations in annual quota levels. In addition, there are still a number of concerns about the spiny dogfish stock condition. The 2009 updated stock assessment shows evidence of strong recruitment; however, low pup production from 1997 through 2003 has been implicated by survey catches of pups and is further supported by subsequent low survey catches of the size categories these age classes have grown into. As such, a decline in the stock is expected when these small 1997–2003 year-classes recruit into the SSB (in approximately 2015). In addition, the current survival rate of pups may be lower than historic levels due to reduced maternal size and a skewed male-to-female sex ratio in the population. A harvest scenario of 21.6 million lb (9,797.6 mt) over the next 5 years has only a 27 percent chance of exceeding the biomass target (½ B_{msy}) when the small year classes from years of low pup production recruit into the fishery.

2010 Specifications and Management Measures

The commercial spiny dogfish quota for FY 2010 is 15 million lb (6,803.89 mt), the level that equates to an F of 0.167 when discard mortality and Canadian harvest estimates are accounted for. In setting the FY 2010 commercial quota at 15 million lb (6,803.89 mt), there is a 98–percent chance that the stock will not decline to the level where it would once again be deemed overfished, and a significant decrease in annual quota levels will not be necessary when the small year-classes from years of low pup production recruit into the fishery.

As specified in the FMP, quota Period 1 (May 1 through October 31) would be

allocated 57.9–percent of the 15–million-lb quota (8,685,000 lb), and quota Period 2 (November 1 through April 30) would be allocated 42.1–percent of the quota (6,315,000 lb). The possession limit of 3,000 lb (1.36 mt) is maintained for FY 2010.

Comments and Responses

NMFS received six comments on the proposed measures from: The Maine Department of Marine Resources (ME DMR); the Mid-Atlantic and New England Fishery Management Councils' Joint Spiny Dogfish Committee (Committee); Shark Advocates International, on behalf of nine conservation organizations including itself; and three individuals.

Comment 1: The Committee supported an increase in the FY 2010 spiny dogfish quota from the 12–million-lb level in the proposed rule, based on analysis of the TRAC results. It specifically supported a commercial quota greater than in the proposed rule (12 million lb) but less than the maximum quota analyzed by the Councils (29.5 million lb), in order to ensure stability in future landings of spiny dogfish.

Response: NMFS considered the Committee recommendation along with the results from the peer reviewed analysis of the TRAC assessment in setting the FY 2010 specifications. NMFS understands the desirability of a constant catch management approach and anticipates that the 15–million-lb (6,803.89 mt) quota for FY 2010 will avoid the need for significant quota fluctuations in future years.

Comment 2: ME DMR suggested NMFS take the TRAC analysis results into account in preparing the final specifications for FY 2010 and increase the commercial quota and possession limit as high as possible. The three individuals, all from Maine, opposed maintaining the 3,000–lb (1.36 mt) possession limit, and suggested it be increased to 6,000 lb. One individual suggested the possession limit increase to either 6,000 lb per day, or 12,000 lb per trip.

Response: NMFS utilized the results from the peer-reviewed analysis of the TRAC when setting the FY 2010 specifications for the spiny dogfish fishery. Although recruitment to the fishery increased in 2009, due to estimated low pup production from 1997–2003 implicated by survey catches of pups and low survey catches of size categories for those year classes, a decline in the stock is expected when these small 1997–2003 year-classes recruit to the SSB (approximately 2015). In addition, the current survival rate of pups may be lower than historic levels due to reduced maternal size and a skewed male-to-female sex ratio in the population. Therefore, the FY 2010 commercial quota is being increased to a level where F is equal to 0.167 after other sources of fishing mortality are accounted for.

NMFS does not agree that the possession limit should be increased for FY 2010. The FMP was developed in 1998 and implemented in 2000 in order to halt large-scale depletion of reproductively mature female spiny dogfish and to allow the stock to rebuild. Because the commercial fishery concentrated primarily on mature females, the FMP established possession limits to control the directed fishery for spiny dogfish and allow for the reproductively mature portion of the population to recover.

Neither the Councils nor the Atlantic States Marine Fisheries Commission (Commission) considered alternatives that would have increased the FY 2010 possession limits. In fact, the Commission plan specifies that spiny dogfish possession limits may be established by the states at a maximum of 3,000 lb (1.36 mt), and many states have set possession limits that are considerably lower than that for some or all of the year. It is for these reasons that the possession limit is maintained at 3,000 lb (1.36 mt) for the FY 2010.

Comment 3: Shark Advocacy International, on behalf of nine conservation groups, including itself, supported maintaining the commercial quota at 12–million-lb (5,443.11 mt) and the possession limit at 3,000–lb (1.36 mt) to ensure the spiny dogfish fishery is fully rebuilt. They state that a significant increase in quota would encourage fishing on already stressed populations of mature females. They also expressed concern about the Commission setting a 15–million-lb (6,803.89 mt) quota because it is inconsistent, in their view, with the best scientific information available. They encouraged NMFS to track state landings, anticipate when catch limits are met, and close Federal fisheries to avoid overages.

Response: NMFS's decision to specify the FY 2010 commercial quota at 15 million lb (6,803.89 mt) is based on new biological reference points established for the spiny dogfish stock, and the determination that the stock is rebuilt.

NMFS concluded that that the commercial quota could be increased to 15 million lb (6,803.89 mt) without negative effects on reproductively mature females. Analysis indicates this quota level equates to an F of 0.167, when discard mortality and Canadian harvest estimates are incorporated into total catch. Projections also indicate that this harvest level could be held constant for 5 years, with a 98–percent probability the stock would not decline to the level where it would once again be deemed overfished.

NMFS does monitor state landings on a weekly basis and closes the fishery when it is anticipated that the commercial quota is met for that quota period; however NMFS and the Commission differ in their quota allocation schemes, which can cause confusion among different parties. NMFS manages the spiny dogfish stock by allocating the quota into two periods, where Period 1 (May 1 through October 31) is allocated 57.9–percent of the commercial quota (8,685,000 lb), and quota Period 2 (November 1 through April 30), which is allocated 42.1–percent of the quota (6,315,000 lb). The Commission allocates the commercial quota by region; the Northern region is allocated 58–percent of the quota, the Southern region is allocated 26–percent of the quota, and North Carolina is allocated 16–percent of the quota. While the Federal fishery is closed when the commercial quota is project to be harvested, it is the responsibility of the individual states to close their fishery at the recommendation of the Commission when the regional allocation is projected to be harvested. Implementing a commercial quota of 15 million lb (6,803.89 mt) ensures consistency with the Commission. However, there are still inconsistencies in the quota allocation scenario between the state and Federal FMPs, which is sometimes confusing for fishermen and creates administrative burden. The issue of quota allocation will be reconsidered by the Councils in upcoming Amendment 3 to the FMP, and is not the subject of this rulemaking.

Classification

Pursuant to section 304 (b)(1)(A) of the Magnuson–Stevens Act, the NMFS Assistant Administrator has determined that this rule is consistent with the Spiny Dogfish FMP, other provisions of the Magnuson–Stevens Act, and other applicable law.

This action is authorized by 50 CFR part 648 and has been determined to be not significant for purposes of Executive Order 12866 (E.O. 12866).

NMFS, pursuant to section 604 of the Regulatory Flexibility Act, has prepared a final regulatory flexibility analysis (FRFA), included in this final rule, in support of the FY 2010 spiny dogfish specifications and management measures. The FRFA describes the economic impact that this final rule,

along with other non-preferred alternatives, will have on small entities.

The FRFA incorporates the economic impacts and analysis summarized in the IRFA, a summary of the significant issues raised by the public, and a summary of analyses prepared to support the action (i.e., the EA and the RIR). The contents of these documents are not repeated in detail here. A copy of the IRFA, the RIR, and the EA are available upon request (see **ADDRESSES**). A complete description of the reasons why this action is being considered, and the objectives of and legal basis for this action, is contained in the preamble to the proposed rule and this final rule, and is not repeated here.

Statement of Objective and Need

A description of the reasons why this action is being considered, and the objectives of and legal basis for this action, is contained in the preamble to the proposed rule and is not repeated here.

Summary of Public Comment on IRFA and Agency Response

NMFS received six comments on this rule but none of them concerned the IRFA or the economic impacts of the proposed action.

Description and Estimate of Number of Small Entities to Which the Rule Will Apply

All of the potentially affected businesses are considered small entities under the standards described in NMFS guidelines because their gross receipts do not exceed $3.5 million annually. Information from FY 2008 was used to evaluate impacts of this action, as that is the most recent year for which data are complete. According to unpublished NMFS permit file data, 3,142 vessels were issued Federal spiny dogfish permits in FY 2008, while 229 of these vessels contributed to overall landings.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

This action does not contain any new collection–of–information, reporting, recordkeeping, or other compliance requirements. It does not duplicate, overlap, or conflict with any other Federal rules.

Minimizing Significant Economic Impacts on Small Entities

The IRFA was revised from the original submitted by the Councils after the results of the TRAC review were announced. The revised IRFA considered four distinct alternatives. Alternative 1, which was the preferred alternative in the proposed rule, is equivalent to No Action, and was proposed to achieve Frebuild = 0.11 with a commercial quota of 12.0–million-lb (5,443.11 mt). Alternative 2 is based on an Ftarget of 0.20, with a resultant commercial quota of 21.6 million lb (9,797.60 mt). Alternative 3 is based on the target F of 0.28 with a resultant quota of 29.5–million-lb (13,380.97 mt). Alternative 4, the action being implemented, is based on an F below the revised Ftarget, and is equal to an F of 0.167 after other sources of fishing mortality are accounted for. Alternative 4 results in a commercial quota of 15.0–million-lb (6,803.89 mt). None of the alternatives proposed to modify the current 3,000–lb (1.36 mt) possession limit.

None of the alternatives under consideration are expected to result in negative economic impacts. Higher quotas (Alternatives 2, 3, and 4) are expected to increase revenue from the dogfish fishery, assuming that the quota implemented would be attained. In general, no negative economic impacts are expected because the alternatives are consistent with the goals of the FMP and are unlikely to result in significant (negative) deviation from the status quo. Total spiny dogfish revenue from the last FY for which data are complete (FY 2008) was reported as $2.157 million. Using the average FY 2008 price/lb ($0.24), landing the full FY 2009 quota (and therefore also the quota under Alternative 1) corresponds to $2.880 million. Using the same approach, landing the 15–million-lb (6,803.89 mt) quota under Alternative 4 would increase revenue to $3.600 million. Revenue would be expected to increase to $5.191 million under Alternative 2, and $7.070 million under Alternative 3. The economic benefits would be greatest under Alternative 3, and to a lesser extent Alternatives 2 and 4, but fishermen would still benefit compared to the maintained revenue levels under Alternative 1. Although Alternatives 2 and 3 would provide the greatest economic benefits, the quota proposed under Alternative 4 is the action being implemented due to concerns about the stock condition and the desire to avoid dramatic fluctuations in annual quota levels, as explained earlier in this preamble. Implementing a commercial quota that employs a constant catch management strategy and that takes into account potential future declines in SSB will provide the industry with a more stable and economically beneficial fishery in the future.

Small Entity Compliance Guide

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as "small entity compliance guides." The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, a letter to permit holders that also serves as small entity compliance guide (guide) was prepared and will be sent to all holders of permits issued for the spiny dogfish fishery. In addition, copies of this final rule and guide (i.e., permit holder letter) are available from the Northeast Regional Administrator (see **ADDRESSES**) and may be found at the following web site: *http://www.nero.noaa.gov/nero/.*

Dated: June 18, 2010

Eric C. Schwaab,

Assistant Administrator For Fisheries, National Marine Fisheries Service.

[FR Doc. 2010–15324 Filed 6–23–10; 8:45 am]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 75, No. 121
Thursday, June 24, 2010

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

5 CFR Parts 1604 and 1651

Uniformed Services Accounts and Death Benefits; Correction

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Proposed rule; correction.

SUMMARY: This proposed rule corrects the **ADDRESSES** section of a proposed rule published in the **Federal Register** on June 18, 2010, regarding uniformed services accounts and death benefits. This correction clarifies that comments may be submitted at *http://www.regulations.gov*, by mail, by hand deliver/courier, or by facsimile.

FOR FURTHER INFORMATION CONTACT: Megan G. Grumbine at (202) 942–1644 or Laurissa Stokes at (202) 942–1645.

Correction

In proposed rule FR Doc. 2010–14741 beginning on page 34654 in the issue of June 18, 2010, correct the **ADDRESSES** section to read as follows: "**ADDRESSES:** You may submit comments using one of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Office of General Counsel, Attn: Thomas Emswiler, Federal Retirement Thrift Investment Board, 1250 H Street, NW., Washington, DC 20005.
- *Hand Delivery/Courier:* The address for sending comments by hand delivery or courier is the same as that for submitting comments by mail.
- *Facsimile:* Comments may be submitted by facsimile at (202) 942–1676.

The most helpful comments explain the reason for any recommended change and include data, information, and the authority that supports the recommended change. We will post all substantive comments (including any personal information provided) without change (with the exception of redaction of SSNs, profanities, et cetera) on *http://www.regulations.gov.*"

Dated: June 21, 2010.

Megan Graziano Grumbine,

Assistant General Counsel.

[FR Doc. 2010–15366 Filed 6–23–10; 8:45 am]

BILLING CODE 6760–01–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1000

[Doc. No. AMS–DA–09–0062; AO–14–A73, et al.; DA–03–10]

Milk in the Northeast and Other Marketing Areas; Correction.

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule; correction.

SUMMARY: This document contains a correction to the proposed rule that was published in the June 14, 2010, **Federal Register** (75 FR 33534). The proposed rule inadvertently used the word "or" rather than "and" in the proposed amendment to § 1000.15 paragraph (b)(1) that provides exceptions to the fluid milk product definition. This document corrects the proposed rule by revising that section and directs that a referendum be conducted on the proposed amendments in the corrected proposed rule.

DATES: *Effective Date:* June 24, 2010.

FOR FURTHER INFORMATION CONTACT: William Francis, Associate Deputy Administrator, USDA/AMS/Dairy Programs, Order Formulation and Enforcement Branches, STOP 0231–Room 2971, 1400 Independence Avenue, SW., Washington, DC 20250–0231, (202) 720–6274, e-mail address: *william.francis@.ams.usda.gov*.

SUPPLEMENTARY INFORMATION: In FR Doc. No. AMS–DA–09–0062 appearing in the **Federal Register** of Monday, June 14, 2010 [75 FR 33534], the following correction is made:

§ 1000.15 [Corrected]

On page 33552, in the second column, in paragraph (b)(1) of § 1000.15, the phrase "Any product that contains less than 6.5 percent nonfat milk solids or contains less than 2.25 percent true milk protein;" is corrected to read "Any product that contains less than 6.5 percent nonfat milk solids and contains less than 2.25 percent true milk protein;".

Further, in consideration of this correction, the Referendum Order to Determine Producer Approval; Determination of Representative Period; and Designation of Referendum Agency on page 33551 of the final decision is superseded by the following order:

Referendum Order To Determine Producer Approval; Determination of Representative Period; and Designation of Referendum Agent

It is hereby directed that a referenda be conducted and completed on or before the 30th day from the date this correction is published in the **Federal Register,** in accordance with the procedures for the conduct of referenda [7 CFR 900.300–311], to determine whether the issuance of the orders as amended and hereby proposed to be amended, regulating the handling of milk in the Northeast, Appalachian, Florida, Southeast, Upper Midwest, Central, Mideast, Pacific Northwest, Southwest and Arizona marketing areas is approved or favored by producers, as defined under the terms of the order, as amended and as hereby proposed to be amended, who during such representative period were engaged in the production of milk for sale within the aforesaid marketing areas.

The representative period for the conduct of such referenda is hereby determined to be June 2009.

The agents of the Secretary of Agriculture to conduct such referenda are hereby designated to be the respective market administrators of the aforesaid orders.

Authority: 7 U.S.C. 601–674 and 7253.

Dated: June 18, 2010.

David R. Shipman,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2010–15296 Filed 6–23–10; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 25

[Docket ID OCC–2010–0010]

RIN 1557–AD34

FEDERAL RESERVE SYSTEM

12 CFR Part 228

[Docket No. R–1387]

RIN 7100–AD50

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 345

RIN 3064–AD60

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Part 563e

[Docket ID OTS–2010–0017]

RIN 1550–AC42

Community Reinvestment Act Regulations

AGENCIES: Office of the Comptroller of the Currency, Treasury (OCC); Board of Governors of the Federal Reserve System (Board); Federal Deposit Insurance Corporation (FDIC); Office of Thrift Supervision, Treasury (OTS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The OCC, the Board, the FDIC, and the OTS (collectively, "the agencies") are issuing this proposed rule to revise provisions of our rules implementing the Community Reinvestment Act (CRA). The agencies propose to revise the term "community development" to include loans, investments, and services by financial institutions that support, enable, or facilitate projects or activities that meet the criteria described in Section 2301(c)(3) of the Housing and Economic Recovery Act of 2008 (HERA) and are conducted in designated target areas identified in plans approved by the United States Department of Housing and Urban Development (HUD) under the Neighborhood Stabilization Program, established pursuant to the HERA and the American Recovery and Reinvestment Act of 2009. The proposed rule would provide favorable CRA consideration to such activities that, pursuant to the requirements of the program, benefit low-, moderate-, and middle-income individuals and geographies in designated target areas. Such consideration would include covered activities within an institution's assessment area(s) and outside of its assessment area(s), as long as the institution has adequately addressed the community development needs of its assessment area(s). As proposed, favorable consideration under the new rule would only be available until no later than two years after the last date appropriated funds for the program are required to be spent by the grantees. The agencies will provide reasonable advance notice to institutions in the **Federal Register** regarding termination of the rule once a date certain has been identified.

DATES: Comments must be received by: July 26, 2010.

ADDRESSES: Comments should be directed to:

Because paper mail in the Washington, DC area and at the agencies is subject to delay, commenters are encouraged to submit comments by the Federal eRulemaking Portal or e-mail, if possible. Please use the title "Community Reinvestment Act Regulation" to facilitate the organization and distribution of the comments.

OCC: You may submit comments by any of the following methods:

- *Federal eRulemaking Portal—"regulations.gov":* Go to *http://www.regulations.gov.* Select "Document Type" of "Proposed Rules," and in "Enter Keyword or ID Box," enter Docket ID "OCC–2010–0010," and click "Search." On "View By Relevance" tab at bottom of screen, in the "Agency" column, locate the proposed rule for OCC, in the "Action" column, click on "Submit a Comment" or "Open Docket Folder" to submit or view public comments and to view supporting and related materials for this rulemaking action.
- Click on the "Help" tab on the Regulations.gov home page to get information on using Regulations.gov, including instructions for submitting or viewing public comments, viewing other supporting and related materials, and viewing the docket after the close of the comment period.
- *E-mail: regs.comments@occ.treas.gov.*
- *Mail:* Office of the Comptroller of the Currency, 250 E Street, SW., Mail Stop 2–3, Washington, DC 20219.
- *Fax:* (202) 874–5274.
- *Hand Delivery/Courier:* 250 E Street, SW., Mail Stop 2–3, Washington, DC 20219.

Instructions: You must include "OCC" as the agency name and "Docket ID OCC–2010–0010" in your comment. In general, OCC will enter all comments received into the docket and publish them on the Regulations.gov Web site without change, including any business or personal information that you provide such as name and address information, e-mail addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this proposed rule by any of the following methods:

- *Viewing Comments Electronically:* Go to *http://www.regulations.gov.* Select "Document Type" of "Public Submissions," in "Enter Keyword or ID Box," enter Docket ID "OCC–2010–0010," and click "Search." Comments will be listed under "View By Relevance" tab at bottom of screen. If comments from more than one agency are listed, the "Agency" column will indicate which comments were received by the OCC.
- *Viewing Comments Personally:* You may personally inspect and photocopy comments at the OCC, 250 E Street, SW., Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 874–4700. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.
- *Docket:* You may also view or request available background documents and project summaries using the methods described above.

Board: You may submit comments, identified by Docket No. R–1387, by any of the following methods:

- *Agency Web site: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/generalinfo/foia/Regs.cfm.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: regs.comments@federalreserve.gov.* Include docket number in the subject line of the message.
- *Fax:* 202/452–3819 or 202/452–3102.
- *Mail:* Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and

Constitution Avenue, NW., Washington, DC 20551.

All public comments are available from the Board's Web site at *http://www.federalreserve.gov/generalinfo/foia/Regs.cfm* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room MP–500 of the Board's Martin Building (20th and C Streets, NW.) between 9 a.m. and 5 p.m. on weekdays.

FDIC: You may submit comments, identified by RIN 3064–AD60 by any of the following methods:

- *Agency Web site: http://www.fdic.gov/regulations/laws/federal.html.* Follow instructions for submitting comments on the Agency Web site.
- *E-mail: Comments@FDIC.gov.* Include the RIN number in the subject line of the message.
- *Mail:* Robert E. Feldman, Executive Secretary, Attention: Comments, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.
- *Hand Delivery/Courier:* Guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7 a.m. and 5 p.m.

Instructions: All submissions received must include the agency name and RIN number. All comments received will be posted without change to *http://www.fdic.gov/regulations/laws/federal.html,* including any personal information provided.

OTS: You may submit comments identified by OTS–2010–0017, by any of the following methods:

- *Federal eRulemaking Portal-"Regulations.gov":* Go to *http://www.regulations.gov,* and follow the instructions for submitting or viewing public comments.
- *Mail:* Regulation Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, Attention: OTS–2010–0017.
- *Fax:* (202) 906–6518.
- *Hand Delivery/Courier:* Guard's Desk, East Lobby Entrance, 1700 G Street, NW., from 9 a.m. to 4 p.m. on business days, Attention: Regulation Comments, Chief Counsel's Office, Attention: OTS–2010–0017.
- *Instructions:* All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received will be entered into the docket and posted on Regulations.gov without change, including any personal information provided. Comments including attachments and other supporting materials received are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.
- *Viewing Comments Electronically:* Go to *http://www.regulations.gov* and follow the instructions for reading comments.
- *Viewing Comments On-Site:* You may inspect comments at the Public Reading Room, 1700 G Street, NW., by appointment. To make an appointment for access, call (202) 906–5922, send an e-mail to *public.info@ots.treas.gov,* or send a facsimile transmission to (202) 906–6518. (Prior notice identifying the materials you will be requesting will assist us in serving you.) We schedule appointments on business days between 10 a.m. and 4 p.m. In most cases, appointments will be available the next business day following the date we receive a request.

FOR FURTHER INFORMATION CONTACT:

OCC: Michael S. Bylsma, Director, or Margaret Hesse, Special Counsel, Community and Consumer Law Division, (202) 874–5750; Greg Nagel or Brian Borkowicz, National Bank Examiner, Compliance Policy, (202) 874–4428, Office of the Comptroller of the Currency, 250 E Street, SW., Washington, DC 20219.

Board: Paul J. Robin, Manager, Reserve Bank Oversight and Policy, (202) 452–3140; or Jamie Z. Goodson, Attorney, (202) 452–3667; Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551.

FDIC: Janet Gordon, Senior Policy Analyst, Division of Supervision and Consumer Protection, (202) 898–3850 or Richard Schwartz, Counsel, Legal Division, (202) 898–7424; Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.

OTS: Stephanie M. Caputo, Senior Compliance Program Analyst, Compliance and Consumer Protection, (202) 906–6549; or Richard Bennett, Senior Compliance Counsel, Regulations and Legislation Division, (202) 906–7409; Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION:

Background

The Community Reinvestment Act (CRA) requires the Federal banking and thrift regulatory agencies to assess the record of each insured depository institution in meeting the credit needs of its entire community, including low- and moderate-income neighborhoods, consistent with the safe and sound operation of the institution, and to take that record into account when the agency evaluates an application by the institution for a deposit facility.[1] The agencies have promulgated substantially similar regulations to implement the requirements of the CRA.[2]

Regulatory Revision

Today, there is a pressing need to provide housing-related assistance to stabilize communities affected by high levels of foreclosures. High levels of foreclosures have devastated communities and are projected to continue into 2012 and beyond with damaging spillover effects for low- and moderate-income census tracts, as well as middle-income census tracts affected by high levels of loan delinquencies and foreclosures. Among the many consequences of high levels of foreclosures are growing inventories of vacant foreclosed properties and institution "other real estate owned" (OREO) properties, depreciating home values, declining property tax bases, and destabilization of communities directly affected by high levels of foreclosures and of adjacent and surrounding neighborhoods.

Neighborhood Stabilization Program (NSP)

Congress recognized the need to provide emergency assistance to address these problems with the establishment of the Neighborhood Stabilization Program (NSP) through Division B, Title III, of the Housing and Economic Recovery Act of 2008 (HERA), Public Law 110–289 (2008). Under HERA, emergency funds ("NSP1"), totaling nearly $4 billion, for the redevelopment of abandoned and foreclosed properties were distributed to States and localities with the greatest need for such funds according to a formula based on the number and percentage of home foreclosures, the number and percentage of homes financed by a subprime mortgage-related loan, and the number and percentage of homes in default or delinquency in each State or unit of general local government. Under NSP1, each of the 50 States and Puerto Rico received a minimum award of $19.6 million and 254 local areas received

[1] 12 U.S.C. 2903.

[2] *See* 12 CFR parts 25, 228, 345, and 563e.

grants totaling $1.86 billion ranging from $2.0 million to $62.2 million.[3]

Using similar criteria, the American Recovery and Reinvestment Act of 2009 (ARRA), Public Law 111–5 (2009), provided supplementary NSP funding ("NSP2") to be awarded as grants, through a competitive bidding process, to State and local governments as well as to non-profit organizations and consortia of non-profit entities. On January 14, 2010, HUD awarded a combined total of nearly $2 billion in NSP2 grants.[4] To receive NSP funding, each grantee was required to submit an action plan or application, including any amendments thereto, to HUD according to specific alternative requirements set out by HUD in 2008 and 2009.[5]

Section 2301(c)(3) of HERA establishes five activities that are "eligible uses" of NSP funds (for purposes of this proposed rule, designated as "NSP-eligible activities"). NSP-eligible activities are projects or activities that use the NSP funds to: (1) Establish financing mechanisms for purchase and redevelopment of foreclosed upon homes and residential properties, including such mechanisms as soft-seconds, loan loss reserves, and shared equity loans for low- and moderate-income homebuyers; (2) purchase and rehabilitate homes and residential properties that have been abandoned or foreclosed upon, in order to sell, rent, or redevelop such homes and properties; (3) establish and operate land banks for homes and residential properties that have been foreclosed upon; (4) demolish blighted structures; and (5) redevelop demolished or vacant properties.[6] In addition, Section 2301(f)(3)(A) of HERA provides that all NSP funds must be used with respect to individuals and families whose income does not exceed 120 percent of the area median income and not less than 25% of funds must be used for the purchase and redevelopment of abandoned or foreclosed homes and residential properties that will be used to house individuals and families whose incomes do not exceed 50 percent of area median income.

Revision of "Community Development" under CRA

The definition of "community development" is a key definition in the agencies' CRA regulations. Financial institutions receive positive consideration in their CRA examinations for community development loans, qualified investments, and community development services, all of which must have a primary purpose of "community development."

The agencies are proposing to revise the interagency CRA regulations by adding to the definition of "community development" loans, investments, and services that support, enable, or facilitate NSP-eligible activities in designated target areas identified in plans approved by HUD under the NSP. For example, under the proposed revised definition of "community development," a financial institution would receive favorable CRA consideration for a donation of OREO properties to non-profit housing organizations in eligible middle-income, as well as low- and moderate-income, geographies. In addition, institutions would receive favorable CRA consideration if they provide financing for the purchase and rehabilitation of foreclosed, abandoned, or vacant properties. Other examples of activities that would receive favorable CRA consideration under the proposal include loans, investments, and services that support the redevelopment of demolished or vacant properties in such areas, consistent with eligible uses for NSP funds.

Allowing institutions to receive CRA consideration for NSP-eligible activities in NSP-targeted areas creates an opportunity to leverage government funding targeted to areas with high foreclosure or vacancy rates. HUD approves NSP action plans and applications, including amendments thereto (hereinafter referred to as "NSP plans" or "plans"), for all NSP grantees. These public documents must designate "areas of greatest need" for targeting NSP-eligible activities, consistent with statutory criteria. Therefore, the agencies propose to provide institutions CRA consideration for supporting NSP-eligible activities, subject to the requirements in Section 2301(c)(3) and the limitations set forth in Section 2301(d)(1)–(3) of HERA, in the geographies identified under these HUD-approved NSP plans. The vast majority of NSP–targeted areas will be listed on a database located on HUD's Web site at: *http://www.hud.gov/nspmaps.* However, there may be a few NSP-targeted geographies in HUD-approved State NSP1 plans that are not identified in the HUD census tract database. Information about these targeted areas may be found in the individual plans.

Although the CRA rules expressly encourage activities that benefit low- or moderate-income individuals or geographies, the agencies have created limited exceptions to cover certain exigencies that may include middle-income individuals and geographies.[7] The agencies believe that the purposes of CRA can be served by providing CRA incentives to institutions to engage in community development loans, investments and services that meet the narrowly tailored requirements of the NSP. First, HUD has stated that its funding of these programs was designed to satisfy Congressional intent that the funds have maximum impact and be targeted to States and local communities with the greatest needs.[8] In addition, while, by its statutory terms, the NSP may include some middle-income individuals, the program must use 25 percent of its funds on low-income individuals and may, in some cases, cover higher percentages of low- and moderate-income individuals.

Under the current CRA rules, an institution is evaluated primarily on how it helps meet the credit and community development needs of its CRA assessment area(s). However, the agencies note that many foreclosed properties owned by an institution may be located in areas that are outside of the institution's CRA assessment area(s). Restricting CRA consideration of NSP-eligible activities to an institution's assessment area(s) may not fully help to promote Congress's objectives for the NSP. Therefore, the proposed rule provides that an institution that has adequately addressed the community development needs of its assessment area(s) may receive favorable consideration for NSP-eligible activities under this provision that are outside of its assessment area(s).

There is precedent for allowing greater flexibility concerning the CRA focus on assessment area(s) in certain temporary and exigent circumstances. For example, in 2006, the agencies issued a supervisory policy statement providing that an institution would receive favorable CRA consideration for engaging in activities that helped

[3] *See Neighborhood Stabilization Grants, http://www.hud.gov/offices/cpd/communitydevelopment/programs/neighborhoodspg/nsp1.cfm.*

[4] *See Neighborhood Stabilization Program 2, http://www.hud.gov/offices/cpd/communitydevelopment/programs/neighborhoodspg/arrafactsheet.cfm.*

[5] 74 FR 21377 (May 7, 2009); 73 FR 58330 (Oct. 6, 2008).

[6] NSP2 funds for redevelopment of demolished or vacant properties may only be used for housing.

[7] 70 FR 44256 (Aug. 2, 2005), and 71 FR 18614 (Apr. 12, 2006).

[8] *See* HUD, NSP Frequently Asked Questions, *http://www.hud.gov/offices/cpd/communitydevelopment/programs/neighborhoodspg/pdf/nsp_faq_formula_allocation.pdf.*

revitalize or stabilize areas affected by Hurricanes Katrina and Rita, even if such areas were not in the institution's assessment area(s), provided the institution had adequately met the CRA-related needs of its assessment area(s).

Finally, the agencies intend for this proposed rule to be generally tied to the duration of the NSP. The NSP does not have a "sunset" date. Under NSP1, grantees must expend NSP funds within four years of the date the grant is awarded. Under NSP2, grantees have three years from that date to fully spend the grant, and HUD was required to obligate all funds appropriated for NSP2 in February 2010. As noted above, the NSP does not have a termination date and Congress could appropriate additional funds for the program. Therefore, a specific termination date for the regulatory provision has not been chosen. Instead, the proposed rule provides that NSP-eligible activities would receive favorable consideration under the new rule if conducted no later than two years after the last date appropriated funds for the program are required to be spent by the grantees. The agencies will provide reasonable advance notice to institutions in the **Federal Register** regarding termination of the rule once a date certain has been identified.

The proposed rule imposes no new requirements on institutions. It simply expands the categories of activities that qualify for CRA considerations as "community development." No institution will be required to provide loans, investments, or services pursuant to the proposed expanded definition. In addition, any community development loans that are made by large institutions under the proposed new provision would be covered under existing loan reporting requirements. As such, no new reporting requirements and negligible, if any, administrative costs will result from the proposed rule. The agencies anticipate that the proposal, if finalized, would provide an incentive for institutions to engage in activities that stabilize foreclosure affected communities approved for NSP projects and, thus, will create an opportunity to leverage government funded projects with complementary private financing in areas targeted for assistance. The likely benefits of the proposed rule are of uncertain magnitude, however, because they cannot be quantified at this time.

Request for Comments

The agencies request comment on all aspects of the proposed rule, and particularly seek comment on:

- Whether the agencies should specify a date certain for the rule to "sunset" and, if so, what that date should be;
- Whether CRA consideration should be limited to those NSP-eligible activities reflected in HUD-approved NSP plans or to activities undertaken by financial institutions that support activities that have been funded by the NSP;
- Recognition of NSP-eligible activities outside of an institution's assessment area(s);
- The potential costs and benefits of the proposed rule if adopted; and
- Whether and the extent to which the proposed rule if adopted will affect an institution's decisions about the amount and type of community development loans, investments, and services it will provide or the geographies it will target in doing so.

In addition, smaller financial institutions are invited to comment on whether any aspects of the proposed rule should be modified to address any implementation issues unique to their lines of business or to provide additional flexibility.

Regulatory Analysis

Request for Comments Regarding the Use of "Plain Language"

Section 722 of the Gramm-Leach-Bliley Act, Public Law 106–102, sec. 722, 133 Stat. 1338, 1471 (Nov. 12, 1999), requires the OCC, Board, FDIC, and OTS to use plain language in all proposed and final rules published after January 1, 2000. Therefore, these agencies specifically invite your comments on how to make this proposed rule easier to understand. For example,

- Have we organized the material to suit your needs? If not, how could this material be better organized?
- Are the requirements clearly stated? If not, how could the regulations be more clearly stated?
- Do the regulations contain language or jargon that is not clear? If so, which language requires clarification?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the regulations easier to understand? If so, what changes to the format would make them easier to understand?
- What else could we do to make the regulations easier to understand?

Regulatory Analysis

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Ch. 3506; 5 CFR 1320 Appendix A.1), each agency reviewed its proposed rule and determined that there are no collections of information. The proposed rule would expand the types of activities that qualify for CRA consideration, if an institution chooses to engage in them, but it would not impose any new requirements, including paperwork requirements. The overall cost of this proposed rule is expected to negligible, at most. The amendments could have a negligible effect on burden estimates for existing information collections, including recordkeeping requirements for community development loans.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires agencies that are issuing a proposed rule to prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of the proposed rule on small entities.[9] The RFA provides that agencies are not required to prepare and publish an initial regulatory flexibility act analysis if the agencies certify that the proposed rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.[10] The Small Business Administration (SBA) has defined "small entities" for banking purposes as a bank or savings association with $175 million or less in assets.[11] 13 CFR 121.201. Each agency has reviewed the impact of this proposed rule on the small entities subject to its regulation and supervision and certifies that it will not have a significant economic impact on a substantial number of the small entities that it regulates and supervises.

OCC: The OCC has reviewed the proposed amendments to Part 25. The proposed rule would expand the definition of the term "community development," which is applied in the CRA regulations' performance tests. However, the proposed rule does not impose new requirements on small entities because the CRA performance test for small entities (as defined above) does not require community development activities. Rather, the proposed rule reduces burden by expanding the types of community development activities for which institutions may receive CRA consideration. Only 617 national banks are small entities based on the SBA's general principles of affiliation (13 CFR 121.103(a)) and the size threshold for

[9] *See* 5 U.S.C. 603(a).

[10] *See* 5 U.S.C. 605(b).

[11] A financial institution's assets are determined by averaging the assets reported on its four immediately preceding full quarterly financial statements.

commercial banks and trust companies. The OCC reviewed national banks with assets of less than $175 million that are evaluated under the lending, investment, and service tests, which are normally applicable to large banks, the community development test, which is applicable to wholesale and limited purpose banks, and the community development performance factor applicable to intermediate small banks. As of March 31, 2010, only 17 of the 617 national banks that are small entities would be required to engage in community development activities under these examination types. The rest would be evaluated under the small bank examination procedures, which do not require consideration of community development activities. Therefore, the OCC has determined that the proposal does not affect a substantial number of small entities.

OTS: The OTS has reviewed the proposed amendments to Part 563e. The proposed rule would expand the definition of the term "community development," which is applied in the CRA regulations' performance tests. However, the proposed rule does not impose new requirements on small entities because the CRA performance test for small entities (as defined above) does not include evaluation of community development activities. Rather, the proposed rule reduces burden by expanding the types of community development activities for which institutions may receive CRA consideration. The Small Business Administration (SBA) has defined "small entities" for banking purposes as a savings association with $175 million or less in assets. *See* 13 CFR 121.201. As of March 31, 2010, only 369 OTS-regulated thrifts are small entities with assets of $175 million or less. However, also as of that date, only two of those small savings associations are wholesale or limited purpose savings associations whose community development activities would be evaluated as part of the CRA examination process. Therefore, the OTS has determined that the proposal does not affect a substantial number of small entities.

FDIC: The FDIC has reviewed the proposed amendments to Part 345. The proposal does not impose new requirements on small entities because the CRA performance test for small entities (as defined above) does not require community development activities. Rather, the proposed rule reduces burden by expanding the types of community development activities for which institutions may receive CRA consideration. As of March 31, 2010, FDIC regulated entities under the SBA's size criteria, with assets of less than $175 million, totaled 2,872. However, also as of that date, only 3 of those banks that are small entities would be required to engage in community development activities under the examination types that include such consideration. Therefore, the FDIC has determined that the proposal does not affect a substantial number of small entities.

Board: In accordance with Section 3(a) of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* the Board has reviewed the proposed amendments to Regulation BB. A final regulatory flexibility analysis will be conducted after consideration of comments received during the public comment period. The Small Business Administration (SBA) has defined "small entities" for banking purposes as a banking organization with $175 million or less in assets. *See* 13 CFR 121.201. The Board invites comment on the effect of the proposed rule on small entities.

1. *Description of rule.* The proposed rule expands the definition of the term "community development," which is applied in the CRA regulations' performance tests. However, it does not impose new requirements on small entities because the CRA performance test for small entities does not require community development activities. Rather, the proposed rule expands the types of community development activities for which institutions may receive CRA consideration.

2. *Reasons for agency action and statement of the objectives/legal basis for the proposal.* As explained above in the supplementary information, the Board believes that it is desirable to expand CRA eligibility to include NSP-eligible activities and areas in order provide financial institutions incentives to leverage NSP funding by providing loans, investments, and services in areas with high foreclosure or vacancy rates. The legal basis of the proposed rule is in CRA Section 806, 12 U.S.C. 2905.

3. *Small entities affected by proposal.* As of December 2009, the Board supervised 403 banking organizations that meet the definition of small entities, all of which are subject to the proposed rule.

4. *Other Federal rules.* The Board is not aware of any other Federal rules which may duplicate, overlap or conflict with the proposed rule.

5. *Significant alternatives to the proposed revisions.* Given that the proposed rule does not require institutions to fund NSP-eligible activities and reduces burdens and restrictions on CRA funding in general, the Board does not believe any other alternatives would accomplish the stated objectives while minimizing burden of the proposed rule. The Board welcomes comment on any significant alternatives that would minimize the impact of the proposal on small entities.

OCC Executive Order 12866 Consideration

Pursuant to Executive Order 12866, OMB's Office of Information and Regulatory Affairs (OIRA) has designated the proposed rule to be significant. It has not yet been determined whether the proposal would have an annual effect on the economy of $100 million or more. OCC solicits comment on the likely increase in lending and costs incurred by banks as a result of this proposed rule. For the final rule, OCC will conduct additional analysis based on information provided by commenters or otherwise obtained during the comment period.

OTS Executive Order 12866 Consideration

Pursuant to Executive Order 12866, OMB's Office of Information and Regulatory Affairs (OIRA) has designated the proposed rule to be significant. It has not yet been determined whether the proposal would have an annual effect on the economy of $100 million or more. OTS solicits comment on the likely increase in lending and costs incurred by savings associations as a result of this proposed rule. For the final rule, OTS will conduct additional analysis based on information provided by commenters or otherwise obtained during the comment period.

OCC and OTS Unfunded Mandates Reform Act of 1995 Determination

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. 1532) requires that covered agencies prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. The OCC and the OTS have determined that this proposed rule will not result in expenditures by State, local, and Tribal governments, or by the private sector, of $100 million or more in any one year. Accordingly,

neither agency has prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

The Treasury and General Government Appropriations Act, 1999—Assessment of Impact of Federal Regulation on Families

The FDIC has determined that this proposed rule will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Public Law 105–277 (5 U.S.C. 601 note).

OCC and OTS Executive Order 13132 Determination

The OCC and the OTS have each determined that its portion of this proposed rule does not have any Federalism implications, as required by Executive Order 13132.

List of Subjects

12 CFR Part 25

Community development, Credit, Investments, National banks, Reporting and recordkeeping requirements.

12 CFR Part 228

Banks, banking, Community development, Credit, Investments, Reporting and recordkeeping requirements.

12 CFR Part 345

Banks, banking, Community development, Credit, Investments, Reporting and recordkeeping requirements.

12 CFR Part 563e

Community development, Credit, Investments, Reporting and recordkeeping requirements, Savings associations.

Department of the Treasury

Office of the Comptroller of the Currency

12 CFR Chapter I

Authority and Issuance

For the reasons discussed in the joint preamble, the Office of the Comptroller of the Currency proposes to amend part 25 of chapter I of title 12 of the Code of Federal Regulations as follows:

PART 25—COMMUNITY REINVESTMENT ACT AND INTERSTATE DEPOSIT PRODUCTION REGULATIONS

1. The authority citation for part 25 continues to read as follows:

Authority: 12 U.S.C. 21, 22, 26, 27, 30, 36, 93a, 161, 215, 215a, 481, 1814, 1816, 1828(c), 1835a, 2901 through 2907, and 3101 through 3111.

2. In § 25.12:

a. Republish the introductory text of paragraph (g):

b. Remove the word "or" at the end of paragraph (g)(3);

c. Remove the period at the end of paragraph (g)(4)(iii)(B) and add in its place "; or"; and

d. Add a new paragraph (g)(5).

The republication and addition read as follows:

§ 25.12 Definitions.

* * * * *

(g) *Community development* means:

* * * * *

(5) Loans, investments, and services that—

(i) Support, enable or facilitate projects or activities that meet the criteria described in Section 2301(c)(3) of the Housing and Economic Recovery Act of 2008 (HERA), Public Law 110–289, 122 Stat. 2654, and are conducted in designated target areas identified in plans approved by the United States Department of Housing and Urban Development in accordance with the Neighborhood Stabilization Program (NSP) established by the HERA and the American Recovery and Reinvestment Act of 2009, Public Law 111–5, 123 Stat. 115;

(ii) Are provided no later than two years after the last date funds appropriated for the NSP are required to be spent by grantees; and

(iii) Benefit low-, moderate-, and middle-income individuals and geographies in the bank's assessment area(s) or areas outside the bank's assessment area(s) provided the bank has adequately addressed the community development needs of its assessment area(s).

* * * * *

Federal Reserve System

12 CFR Chapter II

Authority and Issuance

For the reasons set forth in the joint preamble, the Board of Governors of the Federal Reserve System proposes to amend part 228 of chapter II of title 12 of the Code of Federal Regulations as follows:

PART 228—COMMUNITY REINVESTMENT (REGULATION BB)

3. The authority citation for part 228 continues to read as follows:

Authority: 12 U.S.C. 321, 325, 1828(c), 1842, 1843, 1844, and 2901 *et seq.*

4. In § 228.12:

a. Republish the introductory text of paragraph (g):

b. Remove the word "or" at the end of paragraph (g)(3);

c. Remove the period at the end of paragraph (g)(4)(iii)(B) and add in its place "; or"; and

d. Add a new paragraph (g)(5).

The republication and addition read as follows:

§ 228.12 Definitions.

* * * * *

(g) *Community development* means:

* * * * *

(5) Loans, investments, and services that—

(i) Support, enable or facilitate projects or activities that meet the criteria described in Section 2301(c)(3) of the Housing and Economic Recovery Act of 2008 (HERA), Public Law 110–289, 122 Stat. 2654, and are conducted in designated target areas identified in plans approved by the United States Department of Housing and Urban Development in accordance with the Neighborhood Stabilization Program (NSP) established by the HERA and the American Recovery and Reinvestment Act of 2009, Public Law 111–5, 123 Stat. 115;

(ii) Are provided no later than two years after the last date funds appropriated for the NSP are required to be spent by grantees; and

(iii) Benefit low-, moderate-, and middle-income individuals and geographies in the bank's assessment area(s) or areas outside the bank's assessment area(s) provided the bank has adequately addressed the community development needs of its assessment area(s).

* * * * *

Federal Deposit Insurance Corporation

12 CFR Chapter III

Authority and Issuance

For the reasons set forth in the joint preamble, the Board of Directors of the Federal Deposit Insurance Corporation proposes to amend part 345 of chapter III of title 12 of the Code of Federal Regulations as follows:

PART 345—COMMUNITY REINVESTMENT

5. The authority citation for part 345 continues to read as follows:

Authority: 12 U.S.C. 1814–1817, 1819–1920, 1828, 1831u and 2901–2907, 3103–3104, and 3108(a).

6. In § 345.12:

a. Republish the introductory text of paragraph (g):

b. Remove the word "or" at the end of paragraph (g)(3);

c. Remove the period at the end of paragraph (g)(4)(iii)(B) and add in its place "; or"; and

d. Add a new paragraph (g)(5).

The republication and addition read as follows:

§ 345.12 Definitions.

* * * * *

(g) *Community development* means:

* * * * *

(5) Loans, investments, and services that—

(i) Support, enable or facilitate projects or activities that meet the criteria described in Section 2301(c)(3) of the Housing and Economic Recovery Act of 2008 (HERA), Public Law 110–289, 122 Stat. 2654, and are conducted in designated target areas identified in plans approved by the United States Department of Housing and Urban Development in accordance with the Neighborhood Stabilization Program (NSP) established by the HERA and the American Recovery and Reinvestment Act of 2009, Public Law 111–5, 123 Stat. 115;

(ii) Are provided no later than two years after the last date funds appropriated for the NSP are required to be spent by grantees; and

(iii) Benefit low-, moderate-, and middle-income individuals and geographies in the bank's assessment area(s) or areas outside the bank's assessment area(s) provided the bank has adequately addressed the community development needs of its assessment area(s).

* * * * *

Office of Thrift Supervision

12 CFR Chapter V

For the reasons set forth in the joint preamble, the Office of Thrift Supervision proposes to amend part 563e of chapter V of title 12 of the Code of Federal Regulations as follows:

PART 563e—COMMUNITY REINVESTMENT

7. The authority citation for part 563e continues to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 1467a, 1814, 1816, 1828(c), and 2901 through 2907.

8. In § 563e.12:

a. Republish the introductory text of paragraph (g):

b. Remove the word "or" at the end of paragraph (g)(3);

c. Remove the period at the end of paragraph (g)(4)(iii)(B) and add in its place "; or"; and

d. Add a new paragraph (g)(5).

The republication and addition read as follows:

§ 563e.12 Definitions.

* * * * *

(g) *Community development* means:

* * * * *

(5) Loans, investments, and services that—

(i) Support, enable or facilitate projects or activities that meet the criteria described in Section 2301(c)(3) of the Housing and Economic Recovery Act of 2008 (HERA), Public Law 110–289, 122 Stat. 2654, and are conducted in designated target areas identified in plans approved by the United States Department of Housing and Urban Development in accordance with the Neighborhood Stabilization Program (NSP) established by the HERA and the American Recovery and Reinvestment Act of 2009, Public Law 111–5, 123 Stat. 115;

(ii) Are provided no later than two years after the last date funds appropriated for the NSP are required to be spent by grantees; and

(iii) Benefit low-, moderate-, and middle-income individuals and geographies in the savings association's assessment area(s) or areas outside the savings association's assessment area(s) provided the savings association has adequately addressed the community development needs of its assessment area(s).

* * * * *

Dated: June 16, 2010.

John C. Dugan,

Comptroller of the Currency.

By order of the Board of Governors of the Federal Reserve System, acting through the Secretary of the Board under delegated authority.

Dated: June 15, 2010.

Jennifer J. Johnson,

Secretary of the Board.

Dated at Washington, DC, this 16th day of June 2010.

Valerie J. Best,

Assistant Executive Secretary, Federal Deposit Insurance Corporation.

Dated: May 26, 2010.

By the Office of Thrift Supervision.

John E. Bowman,

Acting Director.

[FR Doc. 2010–15119 Filed 6–23–10; 8:45 am]

BILLING CODE 4810–33–P; 6210–01–P; 6714–01–P; 6720–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 1000

[Docket No. FR–5275–N–10]

Native American Housing Assistance and Self-Determination Reauthorization Act of 2008: Negotiated Rulemaking Committee Meeting

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of negotiated rulemaking committee meeting.

SUMMARY: This document announces the sixth meeting of the negotiated rulemaking committee that was established pursuant to the Native American Housing Assistance and Self-Determination Reauthorization Act of 2008. The primary purpose of the committee is to discuss and negotiate a proposed rule that would change the regulations for the Indian Housing Block Grant (IHBG) program and the Title VI Loan Guarantee program.

DATES: The committee meeting will be held on Tuesday, August 17, 2010, Wednesday, August 18, 2010, and Thursday, August 19, 2010. The meeting will begin at 8 a.m. and is scheduled to end at 5 p.m. on each day.

ADDRESSES: The meeting will take place at the Crowne Plaza St. Paul Hotel—Riverfront, 11 East Kellogg Boulevard, St. Paul, Minnesota 55101; telephone number 651–292–1900 (this is not a toll-free number).

FOR FURTHER INFORMATION CONTACT: Rodger J. Boyd, Deputy Assistant Secretary for Native American Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 4126, Washington, DC 20410; telephone number 202–401–7914 (this is not a toll-free number). Hearing or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

The Native American Housing Assistance and Self-Determination Reauthorization Act of 2008 (Pub. L. 110–411, approved October 14, 2008) (NAHASDA Reauthorization Act) reauthorizes the Native American Housing Assistance and Self-Determination Act of 1996 (25 U.S.C. 4101 *et seq.*) (NAHASDA) through September 30, 2013, and makes a

number of amendments to the statutory requirements governing the Indian Housing Block Grant Program (IHBG) and Title VI Loan Guarantee programs. For more information on the IHBG and Title VI of NAHASDA, please see the background section of the Notice of Negotiated Rulemaking Committee Meeting published on February 22, 2010 at 75 FR 7579.

The NAHASDA Reauthorization Act amends section 106 of NAHASDA to provide that HUD shall initiate a negotiated rulemaking in order to implement aspects of NAHASDA that require rulemaking. On January 5, 2010 (75 FR 423), HUD published a **Federal Register** notice announcing the final list of members of the Native American Housing Assistance & Self-Determination Negotiated Rulemaking Committee.

II. Negotiated Rulemaking Committee Meeting

This document announces the sixth meeting of the Native American Housing Assistance & Self-Determination Negotiated Rulemaking Committee. The committee meeting will take place as described in the **DATES** and **ADDRESSES** sections of this document. The meeting will be open to the public without advance registration. Public attendance may be limited to the space available. Members of the public may be allowed to make statements during the meeting, to the extent time permits, and to file written statements with the committee for its consideration. Written statements should be submitted to the address listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

Dated: June 18, 2010.

Rodger J. Boyd,

Deputy Assistant Secretary for Native American Programs.

[FR Doc. 2010–15364 Filed 6–23–10; 8:45 am]

BILLING CODE 4210–67–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R09–OAR–2010–0336; FRL–9168–1]

Approval and Promulgation of Implementation Plans; Designation of Areas for Air Quality Planning Purposes; State of California; PM–10; Redesignation of the Coso Junction Planning Area to Attainment; Approval of PM–10 Maintenance Plan for the Coso Junction Planning Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve the State of California's request to redesignate to attainment the Coso Junction planning area (CJPA), which is currently designated moderate nonattainment for the particulate matter of ten microns or less (PM–10) national ambient air quality standard (NAAQS). EPA is also proposing to approve the PM–10 emissions inventory and the maintenance plan for the CJPA area, which includes control measures for Owens Lake, the primary cause of PM–10 nonattainment for the CJPA. The California Air Resources Board (CARB) has requested that EPA "parallel process" the redesignation submittal, maintenance plan, and related SIP submissions. Finally, EPA is proposing to find the contribution of motor vehicles to the area's PM–10 problem insignificant. If this insignificance finding is finalized, the area would not have to complete a regional emissions analysis for any transportation conformity determinations necessary in the CJPA.

DATES: Any comments must arrive by July 26, 2010.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2010–0336, by one of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions.
2. *E-mail: lo.doris@epa.gov.*
3. *Mail or Deliver:* Doris Lo (Air-2), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *http://www.regulations.gov* or e-mail. *http://www.regulations.gov* is an "anonymous access" system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Docket: The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available in either location (*e.g.,* CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Doris Lo, EPA Region IX, (415) 972–3959, *lo.doris@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, "we," "us" and "our" refer to EPA.

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C. EPA Has Determined That the Improvement in Air Quality Is Due to Permanent and Enforceable Reductions in Emissions
D. EPA Has Fully Approved a Maintenance Plan, Including a Contingency Plan, for the Area Under Section 175a of the CAA
1. An Attainment Emissions Inventory to Identify the Level of Emissions in the Area Sufficient to Attain the NAAQS
2. A Demonstration Of Maintenance of the NAAQS for 10 Years After Redesignation
3. Verification of Continued Attainment Through Operation of an Appropriate Air Quality Monitoring Network

4. Contingency Provisions That EPA Deems Necessary to Promptly Correct Any Violation of the NAAQS That Occurs After Redesignation of the Area
E. Transportation Conformity And Motor Vehicle Emissions Budgets
IV. Proposed Actions
V. Statutory and Executive Order Reviews

I. Background

The CJPA was originally part of the Searles Valley PM–10 nonattainment area which was designated nonattainment and classified as moderate by operation of law in 1990. *See* 56 FR 11101 (March 15, 1991) and 40 CFR 81.305. In 2002, EPA revised the boundaries of the Searles Valley area, dividing it into three separate nonattainment areas: The CJPA, Indian Wells and Trona. 67 FR 50805 (August 6, 2002). Our recent notices of proposed and final determination of attainment for the CJPA provide more background information on the designation and classification of the area. 75 FR 13710 (March 23, 2010) and 75 FR 27944 (May 19, 2010).

The CJPA is located in eastern California in the southern portion of Inyo County. It is an arid desert area that receives less than 5 inches of rain per year. The area is rural in nature and sparsely populated with only 0.5% of the population of Inyo County (2000 U.S. Census shows 102 people living in the area). The Great Basin Unified Air Pollution Control Agency (GBUAPCD or District) operates the one PM–10 monitoring site for the CJPA which is located in the Coso Junction rest area in the Rose Valley. The Rose Valley is flanked by the Sierra Nevada and Coso mountain ranges. The China Lake Naval Air Weapons Station (China Lake NAWS) covers most of the CJPA and is generally restricted from public access. Air pollution in the CJPA is dominated by windblown dust transported from Owens Lake which has been estimated to be as much as 1.55 million pounds per day and is overwhelming when compared to the daily emissions estimate of 1,478 pounds per day for all of the sources within the CJPA. "2010 PM10 Maintenance Plan and Redesignation Request for the Coso Junction Planning Area," adopted May 17, 2010 (the 2010 Plan).

Owens Lake, which is also located in Inyo County and also under the jurisdiction of the GBUAPCD, is located in the Owens Valley Planning Area which is to the north and adjacent to the CJPA. In 1913, the Los Angeles Department of Water and Power (LADWP) completed an aqueduct system and began diverting the waters of the Owens River to the City of Los Angeles. By 1930, these diversions had drained Owens Lake almost completely dry. Strong winds over the dry, alkaline bed of Owens Lake have produced among the highest measured concentrations of PM–10 ever recorded and can have impacts as far as 150 miles away. See 64 FR 34173, June 25, 1999. The CJPA is anywhere from 10 to 30 miles from the southern end of Owens Lake.

The impact of Owens Lake dust on Coso Junction and other downwind sites was documented in a special purpose monitoring network that was operated from 1993 to 1996. The monitoring network measured Owens Lake dust impacts at five downwind sites and found exceedances of the standard as far as 50 miles from Owens Lake. The five downwind sites included Coso Junction, Navy 1, Pearsonville, Inyokern and Ridgecrest. Navy 1 and Pearsonville are no longer in operation and Inyokern and Ridgecrest are outside the CJPA. *See* the 2010 Plan.

The process for developing controls and a plan for the unique situation at Owens Lake area has been ongoing for decades. The GBUAPCD has developed the controls and plans for the Owens Valley Planning Area with many participants including the California Air Resources Board (CARB), LADWP, the City of Los Angeles, tribal governments, Federal land managers, the Navy, the State Lands Commission, and members of the public. These efforts resulted in a unique Board Order by the GBUAPCD which requires the City of Los Angeles, by certain timeframes, to implement dust control measures including shallow flooding, managed vegetation and application of gravel on designated areas of Owens Lake. 64 FR 34173, June 25, 1999. The original Board Order, which serves as the enforceable mechanism for the dust control measures, has been revised on several occasions and implementation of the dust control measures has led to a 90% decrease in emissions from Owens Lake and to significant improvement in the air quality in CJPA. 2010 Plan.

On May 19, 2010, EPA published a final determination that the CJPA has attained the PM–10 NAAQS and that the area's obligation to submit certain CAA requirements (*i.e.,* demonstration of attainment, demonstration of reasonable further progress, reasonably available control measures, and contingency measures) no longer applies for so long as the area continues to attain prior to final redesignation. Id.

On May 28, 2010, CARB submitted to EPA a request for parallel processing of the "2010 PM10 Maintenance Plan and Redesignation Request for the Coso Junction Planning Area" (the 2010 Plan). The 2010 Plan addresses the PM–10 maintenance plan and the CAA redesignation requirements for the CJPA.

II. The State's Submittal

EPA has granted CARB's request that EPA "parallel process" [1] our review and proposed action on the 2010 Plan's maintenance plan and redesignation request for the CJPA. (*See* May 28, 2010 letter to Jared Blumenfeld, Regional Administrator, EPA Region 9, from James N. Goldstene, Executive Officer, CARB) EPA thus is parallel processing the 2010 Plan, including proposed SIP approvals of the maintenance plan, emissions inventory, and Owens Valley control measures, concurrently with the CARB's adoption process. 40 CFR part 51, appendix V.[2]

The Great Basin Unified Air Pollution Control District (GBUAPCD or District) adopted the 2010 Plan on May 17, 2010 and has forwarded it to CARB. CARB has scheduled a Board Hearing on June 24, 2010 where it will consider approval of the 2010 Plan. All public comments to CARB concerning their proposed action on the 2010 Plan are also due by that date.

III. Proposed Redesignation of the CJPA to Attainment for the PM–10 Standard

Section 107(d)(3)(E) of the CAA sets forth the following criteria for redesignating an area from nonattainment to attainment:

(1) EPA determines that the area has attained the NAAQS.

(2) EPA has fully approved the applicable implementation plan under section 110(k) of the CAA.

[1] Parallel processing is used for expediting the review of a plan. Parallel processing allows a State to submit the plan prior to actual adoption by the State and provides an opportunity for the State to consider EPA comments prior to submittal of the final plan for final review and action.

[2] CARB's parallel processing request and SIP submittal includes the following documents: (1) May 28, 2010 letter to Jared Blumenfeld, Regional Administrator, U.S. EPA Region 9, from James N. Goldstene, Executive Officer, CARB, requesting parallel processing; (2) May 19, 2000 transmittal letter to James N. Goldstene, Executive Officer, CARB, from Theodore D. Schade, Air Pollution Control Officer, GBUAPCD; (3) Proof of Publication of Public Notice for "2010 Maintenance Plan and Redesignation Request for the Coso Junction Planning Area" (2010 Plan) and the May 17, 2010 GBUAPCD Board Hearing; (4) Certification by the Clerk of the GBUAPCD Board regarding adoption of the 2010 Plan; (5) GBUAPCD Board Resolution of Adoption 2010–1 approving and adopting the 2010 Plan; (6) the California Environmental Quality Act Notice of Exemption for the 2010 Plan; (6) the Notice of Public Hearing for consideration of the adoption and approval of the 2010 Plan; and (7) The 2010 PM–10 Maintenance Plan and Redesignation Request for the Coso Junction Planning Area, May 17, 2010, GBUAPCD, with Appendices A–D. All of these documents are available for review in the docket for today's proposed rule.

(3) EPA determines that the improvement in air quality is due to permanent and enforceable reductions in emissions.

(4) EPA has fully approved a maintenance plan for the area as meeting the requirements of section 175A of the CAA.

(5) The State has met all applicable requirements for the area under section 110 and Part D of the CAA.

These requirements are discussed in more detail in a September 4, 1992 EPA Memorandum, "Procedures for Processing Request to Redesignate Areas to Attainment, John Calcagni, Director, Air Quality Management Division" (Calcagni memo). Below, we discuss how these requirements are met for the CJPA.

A. EPA Has Determined That the Area Has Attained the NAAQS

In our May 19, 2010 final determination of attainment, EPA determined that the CJPA attained the PM–10 standard, based on data available to date through 2010.[3] See 75 FR 13710 and 75 FR 27944. Since our May 19, 2010 determination of attainment, the GBUAPCD requested certification of the 2009 data (see letter to Jared Blumenfeld, Regional Administrator, EPA Region 9, from Theodore D. Schade, Air Pollution Control Officer, GBUAPCD). The GBUAPCD recently determined, however, that the monitoring site in Coso Junction has violated siting criteria since January 2010. Following the occurrence of two preliminary exceedances monitored in March 2010, District staff began to investigate the cause of the exceedances. On May 27, 2010, the GBUAPCD's monitoring staff met with the Coso Operating Company's Compliance Officer[4] to assess the situation at the Coso Junction monitoring site. During that meeting and site visit it was determined that the vegetation surrounding the monitor site had not been watered for several years and had died off. As a result, it was no longer providing sufficient ground cover, exposing friable soils that could be lofted by the wind to impact monitor readings. In addition, they found a deterioration in the condition of the unpaved access road to the station, which was located adjacent to the monitor and which had previously been covered with gravel. According to the Coso Operating Company, beginning in January 2010, a contractor working onsite to install an equipment trailer near the monitoring station drove along the access road several times each day in order to collect equipment from the trailer. The lack of vegetation and the contractor activity and increased vehicle trips that forced the gravel deeper into the ground combined to expose soils that could be lofted in close proximity to the monitor. The District staff therefore concluded that beginning in January, 2010, this resulted in the monitoring site's failure to meet EPA siting criteria for a PM–10 monitor. See June 2, 2010 GBUAPCD Memorandum, Subject: Coso Junction PM10 Monitoring Station Siting Review. The District promptly set to work with the Coso Operating Company to resolve the siting problems by re-vegetating the area and adding another layer of gravel to areas with vehicular travel. The Coso Operating Company has also restricted traffic on the unpaved access road adjacent to the monitor, limiting it to only the monitoring station operators and station support personnel as needed. Furthermore, the Company has moved the contractors' trailer, which had previously been parked close to the monitor, to a gravel parking lot approximately 100 meters east of the station. They are developing a plan to apply water to the soil surfaces near the monitor to re-vegetate the area and facilitate development of a ground surface crust that will help minimize localized PM–10 emissions. The GBUAPCD is committed to resolving the monitor siting problem, but believes that until the problem is resolved, the data collected since January 2010 should not be used for regulatory purposes. See June 2, 2010 GBUAPCD Memorandum, Subject: Coso Junction PM10 Monitoring Station Siting Review. The GBUAPCD has advised EPA that adequate application of water to the surrounding soils will begin on July 1, 2010 and that the District expects that, as a result of the efforts outlined above to limit contractor activities near the site and improve the conditions near the monitor, they will be able to rectify the siting problems so that they can once again start collecting valid data subsequently in July.

EPA agrees with the GBUAPCD's assessment of the monitoring site for the period since January 2010 and that the data collected during the first two quarters of 2010 should not be used for regulatory purposes.[5] None of the recorded values have been entered into the AQS database, and, instead, the District has entered codes for the first quarter 2010 data which indicate that the data are invalid due to temporary construction/repair activity in the area. See AQS raw data report for Coso Junction, June 4, 2010. 40 CFR part 58 establishes criteria and requirements for ambient air monitoring and appendix E sets forth the probe and monitoring path siting criteria for ambient air quality monitoring. 71 FR 61236 (October 17, 2006). These include both binding requirements and goals. Section 1(b) of appendix E, the Introduction, provides that "[t]he probe and monitoring path siting criteria discussed in this appendix must be followed to the maximum extent possible." Under the principles established in part 58, appendix E, EPA believes that it is not a reasonable monitoring practice to locate a PM–10 monitor, intended for purposes of characterizing large-scale pollution, so close to a dust source such as the case with the Coso Junction monitor since January 2010. The objective of the Coso Junction monitoring site is to capture transport from Owens Lake which is 15 to 20 miles to the north.

Section 3(a) of appendix E, Spacing from Minor Sources, addresses the siting of monitors, including PM–10 monitors. It states that close spacing between a monitor and a minor source may be proper if the purpose of that monitoring site is to investigate emissions from that source and other local sources. However, if, as is the case with the Coso Junction monitor here, the site is to be used to determine air quality over a larger area representative of many kilometers across, it should not be placed near local, minor sources, because the plume from the local minor source would inappropriately impact the air quality data collected at this site. It is plain that this occurred at the Coso Junction situation, where the monitor, since January 2010, has been operating in an unvegetated area with exposed soils and with unprecedented contractor activity and vehicle traffic traveling frequently on an unpaved access road adjacent to the monitoring site.

EPA will continue to work with the GBUACPD to ensure that the issues with

[3] As discussed in our May 19, 2010 determination of attainment, the GBUAPCD provided preliminary data for 2010 which indicated that there were 2 exceedances in March 2010, but expressed concern about the validity of the data and also noted that the status of these preliminary exceedances could change after the data validation process was concluded and relevant issues addressed. 75 FR 27944. As set forth in the discussion in this section, the GBUAPCD determined that these exceedances, along with the other data for the first quarter of 2010, were invalid due to problems at the monitoring site, and therefore should not be included in the AQS database.

[4] The Coso Operating Company is a power generating company and the owner of the property upon which the Coso Junction monitor is located.

[5] The District advised EPA that among the invalid data monitored during this period was an additional exceedance monitored on May 9.

the monitoring site are resolved as soon as possible. The recent siting problem affects only data collected for the period after January, 2010, and does not have any impact on EPA's determination that the CJPA attained the PM–10 standard based on the two most recent, consecutive three-year periods with quality-assured data. (2006–2008 and 2007–2009). In view of the recent history of continuous attainment in the CJPA and the ongoing expansion of and implementation of controls discussed elsewhere, EPA finds nothing to contradict EPA's belief that the area has attained the PM–10 standard through 2009 and continues to attain to date. Therefore EPA believes that the section 107(d)(3)(E)(i) requirement for attainment has been met.[6]

B. The Area Has Met All Applicable Requirements for Purposes of Redesignation Under Section 110 and Part D of the CAA and the Area Has a Fully Approved Applicable Implementation Plan Under Section 110(K) of the CAA

Section 107(d)(3)(E), as interpreted by EPA, provides that the SIP for the area must be fully approved under section 110(k) of the CAA for all requirements that apply to the area for purposes of redesignation. Section 107(d)(3)(E)(ii) and (v).

EPA may rely on prior SIP approvals in approving a redesignation request. Calcagni Memo, p. 3, *Wall* v. *EPA* F.3d 416 (6th Cir. 2001), *Southwestern Pennsylvania Growth Alliance* v. *Browner,* 144 F.3d 984, 989–90 (6th Cir. 1998), as well as any additional measure it may approve in conjunction with a redesignation action. See 68 FR 25426 (May 12, 2003), and citations therein.

The Calcagni memo states that a state must meet those requirements of section 110 and part D of the CAA that were applicable prior to the submittal of the redesignation request. CAA section 107(d)(3)(E)(v).

1. Basic SIP Requirements Under CAA Section 110

The general SIP elements and requirements set forth in section 110(a)(2) include, but are not limited to, the following: Submittal of a SIP that has been adopted by the state after reasonable public notice and hearing; provisions for establishment and operation of appropriate procedures needed to monitor ambient air quality; implementation of a source permit program; provisions for the implementation of part C requirement for Prevention of Significant Deterioration (PSD); provisions for the implementation of part D requirements for New Source Review (NSR) permit programs; provisions for air pollution modeling; and provisions for public and local agency participation in planning and emission control rule development.

On numerous occasions over the past 35 years, CARB and the GBUAPCD have submitted and we have approved provisions addressing the basic CAA section 110 provisions. There are no outstanding or disapproved applicable section 110 SIP submittals with respect to the State and the GBUAPCD.[7] We propose to conclude that CARB and the GBUAPCD have met all SIP requirements for the CJPA applicable for purposes of redesignation under section 110 of the CAA (General SIP Requirements).

Moreover, we note that SIPs must be fully approved only with respect to applicable requirements for purposes of redesignation in accordance with CAA section 107(d)(3)(E)(ii). Thus, for example, CAA section 110(a)(2)(D) requires that SIPs contain certain measures to prevent sources in a state from significantly contributing to air quality problems in another state. However, the section 110(a)(2)(D) requirements for a state are not linked with a particular nonattainment area's designation and classification in that state. EPA believes that the requirements linked with a particular nonattainment area's designation and classifications are the relevant measures to evaluate in reviewing a redesignation request. The transport SIP submittal requirements, where applicable, continue to apply to a state regardless of the designation of any one particular area in the state. Thus, we do not believe that these requirements should be construed to be applicable requirements for purposes of redesignation.

In addition, EPA believes that the other section 110 elements not connected with nonattainment plan area's attainment status are not applicable requirements for purposes of redesignation. The State will still be subject to these requirements after the CJPA is redesignated. The section 110 and part D requirements, which are linked to a particular area's designation and classification, are the relevant measures to evaluate in reviewing a redesignation request. This policy is consistent with EPA's existing policy on applicability of the conformity SIP requirement for redesignations. *See* Reading, Pennsylvania propose and final rulemakings at 61 FR 53174–53176 (October 10, 1996), 62 FR 24816 (May 7, 1997); Cleveland-Akron-Lorain, Ohio final rulemaking at 61 FR 20458 (May 7, 1996); and Tampa, Florida final rulemaking at 60 FR 62748 (December 7, 1995). See also the discussion of this issue in the Cincinnati redesignation at 65 FR 37890 (June 19, 2000), and in the Pittsburgh redesignation at 66 FR 50399 (October 19, 2001). See also 73 FR 22307, 22312–22313 (April 25, 2008) (San Joaquin PM–10 proposed redesignation). EPA believes that section 110 elements not linked to the area's nonattainment status are not applicable for purposes of redesignation.

2. SIP Requirements Under Part D

Subparts 1 and 4 of part D, title 1 of the CAA contain air quality planning requirements for PM–10 nonattainment areas. Subpart 1 of part D, sections 172(c) and 176 contains general requirements for areas designated as nonattainment. Subpart 4 of part D contains specific planning and scheduling requirements for PM–10 nonattainment areas.

The subpart 1 requirements include, among other things, provisions for the reasonable available control measures (RACM), reasonable further progress (RFP), emissions inventories, contingency measures and conformity.

Subpart 4 of part D, section 189(a), (c) and (e) requirements apply specifically to moderate PM–10 nonattainment areas. These requirements include: (1) An approved permit program for construction of new and modified major stationary sources; (2) an attainment demonstration; (3) provisions for RACM; (4) quantitative milestones demonstrating RFP toward attainment by the applicable attainment date; and (5) provisions to ensure that the control requirements applicable to major stationary sources of PM–10 also apply to major stationary sources of PM–10 precursors except where the Administrator has determined that such sources do not contribute significantly to PM–10 levels which exceed the NAAQS in the area.

In addition to these subpart 4 requirements, general planning requirements in subpart 1, section 172(c) and section 176 include requirements for emissions inventories,

[6] EPA notes that the 2010 Plan also includes air quality modeling to demonstrate that the CJPA is attaining the PM–10 NAAQS. See 2010 Plan, section 6 Air Quality Modeling and Attainment Demonstration and Appendix D. While we do not believe air quality modeling is required to substantiate attainment for this purpose, EPA has reviewed the modeling and believes that it is supportive of the attainment determination.

[7] The applicable California SIP for all nonattainment areas can be found at: *http://yosemite.epa.gov/r9/r9sips.nsf/Casips?readform&count=100&state=California.*

reasonably available control measures, contingency measures and conformity.

For the CJPA, we have determined that the requirements for an attainment demonstration 189(a)(1)(B), section 172(c) and section 189(a)(1)(c) RACM determination, a reasonable further progress demonstration under 189(c)(1) and section 172(c)(9) contingency measures no longer apply for so long as the area continues to attain the PM–10 standard in accordance with EPA's Clean Data Policy. 75 FR 27944. *See also* San Joaquin proposed and final determination of attainment 71 FR 40952, 40954–5 (July 19, 2006) and 71 FR 63641, 63643–7 (October 30, 2006). Moreover, in the context of evaluating the area's eligibility for redesignation, there is a separate and additional justification for finding that the requirements associated with attainment are not applicable for purposes of redesignation. Prior to and independently of the Clean Data Policy, and specifically in the context of redesignations, EPA interpreted attainment-linked requirements as not applicable for purposes of redesignation. In the General Preamble, "General Preamble for the Interpretation of Title I of the Clean Air Act Amendments of 1990," (General Preamble) 57 FR 13498, 13564 (April 16, 1992).

EPA stated that:

> [t]he section 172(c)(9) requirements are directed at ensuring RFP and attainment by the applicable date. These requirements no longer apply when an area has attained the standard and is eligible for redesignation. Furthermore, section 175A for maintenance plans * * * provides specific requirements for contingency measures that effectively supersede the requirements of section 172(c)(9) for these areas.

See also Calcagni memorandum at 6 ("The requirements for reasonable further progress and other measures needed for attainment will not apply for redesignations because they only have meaning for areas not attaining the standard."). Thus, even if the requirements associated with attainment had not previously been suspended, they would not apply for purposes of evaluating whether an area that has attained the standard qualifies for redesignation. EPA has enunciated this position since the General Preamble was published more than eighteen years ago, and it represents the Agency's interpretation of what constitutes applicable requirements under section 107(d)(3)(E). The Courts have recognized the scope of EPA's authority to interpret "applicable requirements" in the redesignation context. *See Sierra Club* v. *EPA,* 375 F.3d 537 (7th Cir. 2004).

After application of the Clean Data Policy, the remaining applicable Part D requirements for moderate PM–10 nonattainment areas include an emissions inventory under section 172(c)(3). In this notice, EPA is proposing to approve the attainment inventories submitted in the 2010 Plan as meeting the requirements for a section 172(c) emissions inventory. See discussion below in section D.1. In addition, EPA has previously approved numerous PM–10 measures into the CJPA SIP. See footnote 11, below, and Table 5 of the 2010 Plan.

With respect to the Part D requirements for a NSR permit program for construction of new and modified major stationary sources, EPA has previously approved new source review rules (Rules 209–A and 216) for the GBUACPD which cover the CJPA. *See* 47 FR 26380 (June 18, 1982) and 41 FR 53661 (December 8, 1976).

Final approval of the NSR program, however, is not a prerequisite to finalizing our proposed approval of the State's redesignation request. EPA has determined in past redesignations that a NSR program does not have to be approved prior to redesignation, provided that the area demonstrates maintenance of the standard without part D NSR requirements in effect. The rationale for this position is described in a memorandum from Mary Nichols, Assistant Administrator for Air and Radiation, dated October 14, 1994, entitled "Part D NSR Requirements or Areas Requesting Redesignation to Attainment." See the more detailed explanations in the following redesignation rulemakings: Detroit, MI (60 FR 12467–12468, March 7, 1996); Cleveland-Akron-Lorrain, OH (61 FR 20458, 20469–20470, May 7, 1996); Louisville, KY (66 FR 53665, 53669, October 23, 2001); Grand Rapids, MI (61 FR 31831, 31836–31837, June 21, 1996); and San Joaquin Valley, CA (73 FR 22307, 22313, April 25, 2008 and 73 FR 66759, 66766–7, November 12, 2008).

The requirements of the PSD program will apply to PM–10 once the area has been redesignated. Thus, new major sources with significant PM–10 emissions and major modifications of PM–10 at major sources as defined under 40 CFR 52.21 will be required to obtain a PSD permit or include PM–10 emissions in their existing PSD permit. Currently, EPA is the PSD permitting authority in the CJPA under a Federal implementation plan. See 40 CFR 52.270(a)(3). However, the GBUAPCD can implement the Federal PSD program through a delegation agreement with EPA or, assuming that the GBUAPCD makes necessary modifications to its NSR rules and EPA approves the modifications, under a SIP-approved rule.

With respect to the conformity requirement, section 176(c) of the CAA requires states to establish criteria and procedures to ensure that federally supported or funded projects "conform" to the air quality planning goals in the applicable SIP. The requirement to determine conformity applies to transportation plans, programs and projects developed, funded or approved under Title 23 U.S.C. and the Federal Transit Act ("transportation conformity") as well as to other federally supported or funded projects ("general conformity"). State conformity revisions must be consistent with Federal conformity regulations relating to consultation, enforcement and enforceability that the CAA required EPA to promulgate.

EPA believes it is reasonable to interpret the conformity SIP requirements as not applying for purposes of a redesignation request under section 107(d) because state conformity rules are still required after redesignation and Federal conformity rules apply where state rules have not been approved. *See Wall* v. *EPA,* 265 F. 3d 426 (6th Cir. 2001), upholding this interpretation. *See also,* 60 FR 62748 (December 7, 1995).

Finally, given the extensive documentation throughout the 2010 Plan and today's proposed rule that the primary cause of the PM–10 problem in the CJPA is windblown dust from Owens Lake, EPA is proposing to determine that major stationary sources of PM–10 precursors do not contribute significantly to PM–10 levels that exceed the standard in the CJPA. Thus, EPA proposes to determine that, if EPA finalizes today's proposal and finally approves the emissions inventory for CJPA, the State has met and EPA has fully approved all requirements applicable under section 110 and part D for the CJPA for purposes of redesignation. CAA Section 107(d)(3)(E)(v).

C. EPA Has Determined That the Improvement in Air Quality Is Due to Permanent and Enforceable Reductions in Emissions

Section 107(d)(3)(E)(iii) requires EPA, in order to approve a redesignation to attainment, to determine that the improvement in air quality is due to emission reductions which are permanent and enforceable. Improvement should not be a result of temporary reductions (*e.g.,* economic

downturns or shutdowns) or unusually favorable meteorology. Calcagni memorandum, p. 4.

As discussed above in the "Background" section, the PM–10 problem in the CJPA is caused primarily by transport of windblown dust from the Owens Lake. Between 1985 and 2009, there have been 22 exceedances of the PM–10 standard, 18 of which were caused by windblown dust from the Owens Lake. The remaining 4 exceedances were caused by windblown dust from agricultural land (1 exceedance in 1990), wildfire smoke (1 exceedance in 2002) and an unpaved truck parking area (2 exceedances in 2007). 2010 Plan, section 3, pp. 4–8. Since 1985, the frequency of exceedances has decreased with the expected number of exceedances per year at in the CJPA ranging from zero to two (prior to 2004 there were many years with six to twelve expected exceedances per year). See 2010 Plan, Table 3.

SUMMARY OF 24-HOUR PM–10 MAXIMUM EXCEEDANCES (μG/M³) IN THE CJPA (1985 THROUGH 2009)*

Exceedance date	Conc. (μg/m³)	Primary cause of exceedance
4/25/1985	307	Owens Lake Dust.
4/2/1986	1175	Owens Lake Dust.
6/7/1986	157	Owens Lake Dust.
1/15/1987	196	Owens Lake Dust.
2/3/1989	227	Owens Lake Dust.
4/23/1990	866	Abandoned Ag Land Dust.
10/26/1993	254	Owens Lake Dust.
12/23/1993	188	Owens Lake Dust.
1/5/1994	388	Owens Lake Dust.
4/8/1995	692	Owens Lake Dust.
4/9/1995	567*	Owens Lake Dust.
4/21/1995	337	Owens Lake Dust.
4/27/1996	176*	Owens Lake Dust.
5/23/1996	309	Owens Lake Dust.
3/6/1998	246*	Owens Lake Dust.
3/18/1998	409	Owens Lake Dust.
7/25/2002	175	Wildland Fire Smoke.
2/2/2003	484	Owens Lake Dust.
12/28/2006	296	Owens Lake Dust.

SUMMARY OF 24-HOUR PM–10 MAXIMUM EXCEEDANCES (μG/M³) IN THE CJPA (1985 THROUGH 2009)*—Continued

Exceedance date	Conc. (μg/m³)	Primary cause of exceedance
6/5/2007	217	Coso Junction Parking Area Dust.
12/6/2007	283	Coso Junction Parking Area Dust.
12/22/2009	168	Owens Lake Dust.

* All values were recorded at the Coso Junction monitor site with the following exceptions: 4/9/1995 at Navy, 4/27/1996 at Pearsonville and 3/6/1998 at Navy. See 2010 Plan, Tables 1 and 2.

Control Measures for Owens Lake

As discussed above, the Owens Valley Planning Area is located to the north and adjacent to CJPA and is classified as a serious PM–10 nonattainment area. Attainment in the CJPA depends on controls on and emissions reductions from Owens Lake which is the primary source of emissions in the Owens Valley Planning area. The GBUAPCD has jurisdiction over air quality planning requirements for Inyo, Mono and Alpine Counties. The GBUAPCD has adopted the following plan and revisions for the Owens Valley Planning Area, in order to reduce the PM–10 emissions from Owens Lake:

- In 1998 the GBUAPCD adopted and CARB submitted the Owens Valley SIP requiring dust controls on 16.5 square miles of the Owens lakebed. (1998 Owens Valley SIP).
- In 2003 the GBUAPCD adopted and CARB submitted a SIP revision to expand dust controls to cover a total 29.8 square miles of the Owens lakebed. (2003 Owens Valley SIP revision).
- In 2008 the GBUAPCD adopted and CARB submitted a SIP revision to expand dust control requirements to apply to a total of 43.1 square miles of the Owens lakebed. (2008 Owens Valley SIP revision).

See 2010 Plan, section 5, pp. 11–12. EPA has approved the 1998 Owens Valley SIP (64 FR 48305, September 3, 1999), but has not acted on the State's proposed 2003 and 2008 Owens Valley SIP revisions. In the meantime, the GBUAPCD has implemented the 2003 Owens Valley SIP revision submission measures and has begun implementation of the 2008 Owens Valley SIP submission measures.

The GBUAPCD, which exercises joint jurisdiction over CJPA and Owens Valley, has shown that attainment and maintenance of the PM–10 standard in the CJPA relies in large part on the control measures in place for the Owens Valley Planning Area through 2008. Thus, the GBUAPCD has included in its maintenance plan submission for the CJPA area all of the control measures in the 1998 Owens Valley SIP, as well as the 2003 and 2008 SIP revisions for Owens Valley that the District and CARB have submitted to EPA. These control measures are contained in the CJPA 2010 Plan, Appendix C, GBUAPCD Board Order #080128–01, January 28, 2008/February 1, 2008 (Board Order).[8] [9] The 2010 Plan indicates that all of the controls required by the 1998 Owens Valley SIP and the District's 2003 Owens Valley SIP revision submission (*i.e.,* dust controls for 29.8 square miles of the Owens lakebed) have been successfully implemented and that the controls have led to a decline in the level of frequency of PM–10 exceedances of the 24-hour standard in the CJPA. 2010 Plan, section 5, p. 12 and Table 3.[10] The additional controls required by the 2008 SIP revision (for a total of 43.0 square miles of controls on Owens Lake) are scheduled for implementation by October 2010.

Prior to the adoption of the 1998 Owens Valley PM–10 SIP, the peak 24-hour PM–10 concentration levels recorded in the CJPA were as high as 1175 micrograms per cubic meter (μg/m³) with many years recording levels over 300 μg/m³, and there were several years where the expected number of exceedances were as high as 6 or 12 days. See 2010 Plan, Table 3 and Summary of 24-hour PM–10 Maximum Exceedances table above. Following the adoption of the 1998 Owens Valley SIP and the 2003 Owens Valley SIP

[8] Adopted on February 1, 2008, the GBUAPCD Board Order #080128–01 provides for the enforcement and implementation of 43.0 square miles of BACM level controls on the Owens Lake bed found in the 1998 Owens Valley SIP and subsequent SIP revisions. Board Order #080128–01 specifies the timing, implementation, placement, and management of lake bed controls such as shallow flooding, managed vegetation, gravel blanketing, and "moat and row" controls. Also, Board Order #080128–01 provides for contingency procedures for supplemental controls, maintenance of existing controls, and a "performance monitoring plan."

[9] We note that there is a slight difference between the discussion in the 2010 Plan (p. 12) and the Board Order (paragraph 5) for the total square miles controlled. Page 12 of the 2010 Plan states the total is 43.1 square miles while the Board Order states the total is 43.0 square miles. Since the Board Order is the enforceable mechanism, we believe the enforceable controls are for 43.0 square miles.

[10] Table 3 of the 2010 Plan shows a decline in level and frequency of the 24-hour PM–10 standard. Table 3 also provides information on the annual PM–10 standard, however, EPA revoked this standard on October 17, 2006, effective on December 18, 2006 (71 FR 61144).

revision, which have led to implementation of 29.8 square miles of dust controls on Owens Lake by the end of 2006, the peak 24-hour PM–10 levels and expected number of exceedances have declined. *Id.* Figure 4 of the 2010 plan also documents the dramatic decrease in emissions in Owens Valley. EPA believes that the data in Table 3 and Figure 4 of the 2010 plan show there is a direct air quality benefit in the CJPA from the dust controls implemented for Owens Lake.

Control Measures in the CJPA

As mentioned above, 4 of the 22 PM–10 exceedances in the CJPA between 1985 and 2009 were caused by sources other than Owens Lake emission including windblown dust from an agricultural field, smoke from a wildfire and windblown dust from an unpaved truck parking area. 2010 Plan, section 3, p. 4. These types of exceedances are not generally a problem in the CJPA and are not expected to recur. The agricultural land just north of the monitor site was stabilized by natural vegetation cover in 1991 after the land was fallowed. Since that time no agricultural activities have taken place in the CJPA. Dust from the unpaved truck parking area, located adjacent to the PM–10 monitor site was mitigated by covering it with gravel in 2008 and then asphalt pavement in 2009. 2010 Plan, section 1. The 2010 Plan also provides a summary of the District rules and regulations that apply to sources of PM–10 within the CJPA. 2010 Plan, Table 5. While the focus of attaining and maintaining the PM–10 standard in the CJPA is on the controls for Owens Lake, these measures, many of which have been SIP-approved, will also benefit air quality.[11] Those measures that EPA has already approved into the CJPA SIP contribute to attainment and maintenance of the PM–10 NAAQS.

EPA Proposal for Approval of GBUAPCD Board Order Maintenance Plan Control

EPA is proposing to approve the GBUAPCD Board Order #080128–01, January 28, 2008/February 1, 2008, which is included as Appendix C of the 2010 Plan. As discussed above, this Board Order is the enforceable mechanism by which the GBUAPCD can require the City of Los Angeles to implement, in phases, a total of 43 square miles of dust control measures for Owens Lake. The successful implementation of 29.8 square miles of controls by December 2006 has resulted in significantly improved air quality in the CJPA. 2010 Plan, Table 3, Figure 4, section 5. Thus, EPA believes that the improvement in PM–10 air quality for the CJPA is the result of permanent and enforceable reductions in emissions from Owens Lake, and that this improvement will continue if our proposal is finalized. Because of the clear correlation between the reductions in emissions from Owens Lake and declining PM–10 exceedances in the CJPA, EPA believes that the improvement in air quality is not the result of temporary reductions (e.g., economic downturns or shutdowns) or unusually favorable meteorology. Thus, EPA proposes to determine that the improvement in air quality in CJPA is due to permanent and enforceable emissions reductions 107(d)(3)(E)(iii).

D. EPA Has Fully Approved a Maintenance Plan for the Area Under Section 175A of the CAA

Section 175A of the CAA provides the requirements for maintenance plans that must be fully approved under section 107(d)(3)(E) for purposes of redesignation to attainment. The provisons to be included in a maintenance plan are further addressed in the Calcagni memo. They include:

(1) An attainment emissions inventory to identify the level of emissions in the area sufficient to attain the NAAQS;

(2) A demonstration of maintenance of the NAAQS for 10 years after redesignation;

(3) Verification of continued attainment through operation of an appropriate air quality monitoring network; and

(4) Contingency provisions that EPA deems necessary to assure that the State will promptly correct any violation of the NAAQS that occurs after redesignation of the area. We discuss below how these requirements are met for the SJVAB.

1. An Attainment Emissions Inventory To Identify the Level of Emissions in the Area Sufficient To Attain the NAAQS

Section 172(c)(3) of the CAA requires plan submittals to include a comprehensive, accurate, and current inventory of actual emissions from all sources in the nonattainment area. In demonstrating maintenance in accordance with CAA section 175A and the Calcagni memo, the State should provide an attainment emissions inventory to identify the level of emissions in the area sufficient to attain the NAAQS. Where the State has made an adequate demonstration that air quality has improved as a result of the SIP, the attainment inventory will generally be an inventory of actual emissions at the time the area attained the standard. EPA's primary guidance in evaluating these inventories is the document entitled, "PM–10 Emissions Inventory Requirements," EPA, OAQPS, EPA–454/R–94–033 (September 1994) which can be found at: *http://www.epa.gov/ttn/chief/eidocs/pm10eir.pdf.*

The 2010 Plan provides an estimated daily PM–10 emissions inventory for 2008 through 2025. The year 2008 was chosen as the attainment year because it is one of the attainment years in the most recent three-year periods (2006–2008, 2007–2009) in which compliance with the PM–10 NAAQS was monitored. The 2010 Plan projects the emissions attainment inventory to remain constant from 2008 through 2025, at an estimated 1,478 pounds per day. See 2010 Plan, section 4, pp. 9–10. In contrast, as noted in the Background discussion in section I above, the emissions generated within the CJPA are less than 0.1% of the emissions caused by windblown dust from the Owens Lake area, which were estimated to be 1.55 million pounds per day for the CJPA design day (January 5, 2007). *Id.*

DAILY PM–10 EMISSIONS FOR 2008 THROUGH 2025 FOR PM–10 SOURCES IN THE CJPA

	Pounds per day
Stationary Sources:	
—California Lightweight Pumice	167
—China Lake Naval Air Weapons Station	84

[11] There are thirteen measures listed in Table 5 of the 2010 Plan including New Source Review and permitting rules and rules to control fugitive dust and controlled burning. We have approved nine of these rules into the SIP: Rule 209–A, 47 FR 26380, June 18, 1982; Rule 216, 41 FR 53661, December 8, 1976; Rule 400, 42 FR 28883, June 6, 1977; Rule 401, 42 FR 28883, June 6, 1977; Rule 408, 46 FR 8471, January 27, 1981; Rule 409, 42 FR 28883, June 6, 1977; Rule 410, 42 FR 28883, June 6, 1977; and, Regulation XIII (Rules 1301–1311), 64 FR 19916, April 23, 1999.

DAILY PM–10 EMISSIONS FOR 2008 THROUGH 2025 FOR PM–10 SOURCES IN THE CJPA—Continued

	Pounds per day
—Coso Operating Company	953
—Halliburton Services	20
—Twin Mountain Rock	58
—Total Stationary	1282
Area Sources:	
—Unpaved Roads	83
—Paved Roads	101
—Total Area Sources	184
Mobile Sources:	
—On-Road Motor Vehicles	12
Total PM–10 for CJPA	1478
Source: 2010 Plan, Table 4.	

The 2010 Plan's inventory for sources within the CJPA is subdivided into three subcategories: Stationary sources; area sources; and mobile sources. *Id.* In the CJPA, the majority of daily PM–10 emissions are estimated to come from stationary sources. Five sources account for 1,282 pounds or 86.7% of estimated total daily PM–10 emissions. The largest stationary source contributor is Coso Operating Company, a geothermal, wind and solar energy company, with an estimated 953 pounds per day of PM–10 emissions. These emissions estimates are derived from GBUAPCD source permits and include unpaved road and haul road PM–10 emissions for these sources. *Id.*

The plan estimates daily area source emissions for unpaved and paved roads at 184 pounds per day (12.4% of total).

CJPA on-road mobile source emissions are estimated to be 12 pounds per day (0.8% of total) and are based on CARB's 2008 PM–10 emission estimates for Inyo County. CJPA estimates were derived from Inyo County estimates by pro-rating the amount of traffic (5.1%) in the CJPA. 2010 Plan, section 4, p. 10.

GBUAPCD projects that PM–10 emissions will not grow from 2008 to 2025 because of the CJPA's continued sparse population and lack of population growth, and relative stability of the area's industrial activities. The CJPA has only 0.5% of Inyo County's population and, according to U.S. Census Bureau figures, Inyo County population declined from 18,281 in 1990 to 17,945 in 2000, and further declined to 17,136 in 2008, a population decrease of 4.5% over this 18-year period. 2010 Plan, section 4, p. 9–10.

In conclusion, EPA believes that the selection of 2008 as the attainment year inventory and 2025 for the maintenance year inventory is appropriate since the area was determined to have attained by 2008, and that given the sparse population, the lack of population growth and the lack of changes to industrial operations for the area, a constant inventory of 1,478 pounds per day from 2008 through 2025 is also appropriate for the CJPA. We have reviewed the 2010 Plan's estimated attainment year emission inventory and determined that it is current, accurate and comprehensive, and meets EPA guidance and the CAA. Therefore we are proposing to approve the 2008 inventory, which also serves as the maintenance plan's attainment year inventory, under section 172(c) of the CAA.

2. A Demonstration of Maintenance of the NAAQS for 10 Years After Redesignation

Section 175A of the CAA requires a demonstration of maintenance of the NAAQS for 10 years after redesignation. A state generally may demonstrate maintenance of the NAAQS by either showing that future emissions of a pollutant or its precursors will not exceed the level of the attainment inventory, or by modeling to show that the future anticipated mix of sources and emission rates will not cause a violation of the NAAQS.

As discussed above, the emissions reductions from Owens Lake provided the path to attainment for the CJPA and is also the paramount source of emissions that must be addressed in ensuring maintenance for the area. The emissions estimates and projections for the Owens Lake and the Owens Valley area have decreased significantly since 2000 and are expected to continue to decrease until 2011 and then remain constant through 2025. 2010 Plan, section 5, pp. 11–13 and Figure 4. Figure 4 of the 2010 Plan shows actual and forecasted emissions from Owens Lake and from all sources in the Owens Valley area. Since 2000, the actual emissions have decreased by 90% as a result of dust control measures and the forecasts show emission from Owens Lake and the Owens Valley Area either staying constant or decreasing from 2007 through 2026. EPA believes the forecasted decreases in emissions in 2010 from Owens Lake are consistent with the additional control measures (discussed above) that are scheduled for implementation.

In addition, we believe that, while not nearly as significant as the emissions reductions from Owens Lake, as discussed in the Inventory section above the total daily emissions of PM–10 from sources within CJPA will remain constant at 1,478 pounds per day from 2008 through 2025. 2010 Plan, section 4. Sources within the CJPA are also subject to SIP-approved measures. See footnote 11.

Based on our review of the information presented in the 2010 Plan, we believe that the State has shown that attainment of the PM–10 standard will be maintained in the CJPA for at least ten years after redesignation.

3. Verification of Continued Attainment Through Operation of an Appropriate Air Quality Monitoring Network

In demonstrating maintenance, continued attainment of the NAAQS can be verified through operation of an appropriate air quality monitoring network. The Calcagni memo states that the maintenance plan should contain provisions for continued operation of air quality monitors that will provide such verification.

The GBUAPCD has committed to continue daily monitoring of PM–10 at the Coso Junction monitoring site and is authorized to do so under the California Health and Safety Code section 40001. 2010 Plan, section 5.1, p. 13 and section 10, p. 23. The Coso Junction monitor is part of an EPA-approved air quality monitoring network. See December 1, 2009 letter to Ted Schade, Air Pollution Control Officer, GBUAPCD, from Joseph Lapka, Acting Manager, Air Quality Analysis Section, EPA Region 9. As noted above, EPA and the District have

recently learned that changed conditions in the area adjacent to the Coso Junction monitor have resulted in the monitor not meeting EPA siting criteria since January 2010. As a result, data from the monitor during this period are not representative of the area for which the monitor is designed, and cannot be relied upon for regulatory purposes. GBUAPCD has already taken steps to correct the problems identified, which are linked to the operations of a nearby contractor. These include plans and actions to promote regrowth of vegetation in the area surrounding the monitor, and development of a competent crustal surface to reduce emissions. The GBUAPCD has already rerouted and restricted traffic from an unpaved access road near the monitor, and has directed the contractor to remove its equipment trailer from a location near the monitor. Additional gravel placement on the access road and areas on which vehicles will travel and the application of water will also reduce dust emissions near the monitor. The GBUAPCD is committed to resolving the siting issues and expects that the monitor will be collecting valid data for the area after July 1, 2010. Thus EPA believes that all these circumstances demonstrate that the District's commitment to continued verification through operation of its monitor is credible and sufficient.

4. Contingency Provisions That EPA Deems Necessary To Promptly Correct Any Violation of the NAAQS That Occurs After Redesignation of the Area

Contingency provisions are required for maintenance plans under section 175A of the CAA. These contingency measures are distinguished from those generally required for nonattainment areas under section 172(c)(9) in that they are not required to be fully adopted measures that will take effect without further action by the state in order for the maintenance plan to be approved. The Calcagni memo states that the contingency provisions of the maintenance plan should identify the measures to be adopted, a schedule and procedure for adoption and implementation, and a time limit for action by the state. The memo also states that the contingency provisions should identify indicators or triggers which will be used to determine when the contingency measures need to be implemented. While the memo suggests inventory or monitoring indicators, it states that contingency provisions will be evaluated on a case-by-case basis.

As discussed in section C above, EPA is proposing to approve the GBUAPCD Board Order #080128–01 for Owens Lake dust controls as part of the maintenance plan for the CJPA. The Board Order is the enforceable mechanism by which the GBUAPCD requires the City of Los Angeles to implement, in phases, a total of 43 square miles of dust control measures for Owens Lake. EPA believes that the successful implementation of 29.8 square miles of controls by December 2006 has let to significantly improved air quality in the CJPA and in fact has resulted in attainment of the PM–10 standard in the CJPA, beginning in 2008. Thus, EPA also believes that additional dust controls beyond the 29.8 square miles of control, and implemented after attainment, can serve as contingency measures for the CJPA. The additional controls included in the 2008 Board Order which EPA is today proposing to approve, include application of another 13.2 square miles of dust controls to Owens Lake by October 31, 2010. 2010 Plan, section 5. Since the primary source of PM–10 emissions is from Owens Lake, EPA is proposing to approve the 13.2 square miles of dust controls for Owens Lake as meeting the requirement for 175A maintenance plan contingency measures for the CJPA. These dust controls for an additional 13.2 square miles of Owens Lake are already adopted controls and do not require a trigger for implementation.

EPA has long approved contingency provisions that rely on reductions from measures that are already in place but are over and above those relied on for attainment and RFP under CAA section 172(c)(9). See, *e.g.,* 62 FR 15844 (April 3, 1997); 62 FR 66279 (December 18, 1997); 66 FR 30811 (June 8, 2001); 66 FR 586 and 66 FR 634 (January 3, 2001). See discussion in our final PM–2.5 implementation rule. 72 FR 20586, 20642–20643 (April 25, 2007). This interpretation has also been upheld in *LEAN* v. *EPA,* 382 F.3d 575 (5th Cir. 2004), where the court in that case set forth its reasoning for accepting excess reductions from already adopted measures as contingency measures.

Our interpretation that excess emission reductions can appropriately serve as section 172(c)(9) contingency measures is equally applicable to section 175A(d) contingency measures. EPA has approved maintenance plans under section 175A that included contingency provisions relying on measures to be implemented prior to any post-redesignation NAAQS violation. *See* 60 FR 27028, 27029 (May 22, 1995); 73 FR 66759, 66,769 (November 12, 2008).

The Board Order also includes contingency measures for the Owens Valley Planning Area that are intended to address the CAA section 172(c)(9) contingency measure requirement for nonattainment area plans. The process for developing these contingency measures for Owens Lake is triggered by a determination by the GBUAPCD Air Pollution Control Officer (APCO) as described in paragraphs 10 through 13 of the Board Order. As paragraph 10 explains, these are annual determinations made by the GBUAPCD APCO beginning in 2011. Paragraph 11 of the Board Order provides criteria and procedures for determining the need for contingency measures and supplemental control measures. Paragraph 13 ensures that the GBUAPCD can require the City of Los Angeles to take added reasonable measures not specifically addressed within paragraphs 10 or 12. EPA believes these procedures for additional measures at Owens Lake, which EPA is today proposing to approve, will also help to ensure continued attainment in the CJPA.

Although local emissions within CJPA play a very minor role in maintenance of the PM–10 standard in CJPA, EPA notes that in addition to the 175A maintenance plan contingency measures directed at Owens Valley that we are proposing to approve, the GBUAPCD has also made a commitment to address local emissions in CJPA. GBUAPCD commits to investigate the cause of any such exceedance within 60 days from the end of the calendar quarter in which the exceedance occurs, and to address and correct exceedances found to be caused by local sources within 18 months of identifying the cause of the exceedance. See 2010 Plan, sections 5.1 and 10 and June 10, 2010 letter to Deborah Jordan, Director, Air Division, EPA Region 9, from Theodore D. Schade, Air Pollution Control Officer, GBUAPCD. EPA believes this commitment will also help to ensure maintenance in the CJPA.

Finally, GBUAPCD is not proposing to remove or cease implementing any approved SIP measures. Thus, for the reasons set forth above, EPA is proposing to approve the contingency measures under section 175A(d).

In light of the discussion set forth above, EPA is proposing to approve the maintenance plan for CJPA as meeting the requirements of CAA section 175A.

E. Transportation Conformity and Motor Vehicle Emissions Budgets

Under section 176(c) of the CAA, transportation plans, programs and projects in the nonattainment or maintenance areas that are funded or approved under title 23 U.S.C. and the

Federal Transit Laws (49 U.S.C. chapter 53) must conform to the applicable SIP. In short, a transportation plan and program are deemed to conform to the applicable SIP if the emissions resulting from the implementation of that transportation plan and program are less than or equal to the motor vehicle emissions budget (MVEB) established in the SIP for the attainment year, maintenance year and other analysis years. See, generally, 40 CFR part 93.

Section 93.109(m) of EPA's regulations implementing the transportation conformity requirement (40 CFR part 93) states that an area is not required to satisfy a regional emissions analysis for a pollutant if EPA finds that motor vehicle emissions of that pollutant are an insignificant contributor to the area's air quality problem. To make this demonstration, the SIP would have to show that it would be unreasonable to expect that the area would experience enough motor vehicle emissions growth in that pollutant/precursor for a NAAQS violation to occur. Factors to consider in such a demonstration include the following: the percentage of motor vehicle emissions in the context of the total SIP inventory; the current state of air quality as determined by monitoring data for that NAAQS; the absence of SIP motor vehicle control measures; and historical trends and future projections of the growth of motor vehicle emissions.

Today, we are proposing to find that motor vehicle-related PM–10 emissions (*i.e.,* tailpipe emissions, brake and tire wear emissions, and re-entrained dust emissions from paved and unpaved roads) are insignificant contributors to the CJPA's PM–10 nonattainment problem, based on our consideration of the factors identified in EPA's transportation conformity regulations and on the unique circumstances of the PM–10 CJPA.

As discussed in section 4 of the 2010 Plan, at 196 pounds per day, the total on-road-related PM–10 emissions from motor vehicles are 13.3% of the 1,478 pounds per day attainment inventory for the CJPA. However, as explained elsewhere in this notice, air pollution in the CJPA is dominated by windblown dust transported from Owens Lake, which has been estimated to be as much as 1.55 million pounds per day. The contribution of Owens Lake to the CJPA is overwhelming when compared to the daily emissions estimate of 1,478 pounds per day for all of the sources within the CJPA, and is even more overwhelming when compared to the on-road PM–10 emissions of 196 lbs/day. In comparison with the lowest projected annual PM–10 emissions levels for the Owens Valley, 8,000 tons per year, CJPA motor vehicle related PM–10 emissions are insignificant at 196 pounds per day (35.8 tons per year), which means that on-road motor vehicle emissions represent just 0.4% of the inventory when emissions from Owens Valley are considered.[12] EPA further notes that the four exceedances attributed to CJPA sources were caused by windblown dust from fallow agricultural land, wildfire smoke and an unpaved truck parking area. See 2010 Plan, section 3, pp. 4–9. As discussed above and in the 2010 Plan, exceedances due to these sources are not expected to recur because the agricultural land has been re-vegetated and the truck parking lot has been paved.

While EPA indicated in its Transportation Conformity final rule that mobile source emissions of approximately 10% or less may be considered insignificant, EPA further noted that ten percent should be viewed as a general guideline only, and that mobile source emissions that are above 10% of total emissions could still be found to be insignificant, depending on the circumstances. Given the unique circumstances of the CJPA, EPA believes that the motor vehicle emissions contribution to the CJPA is insignificant.

In addition to the overwhelming contribution of Owens Valley to the CJPA PM–10 problem, EPA considered the control measures adopted for Owens Valley as one of the relevant factual circumstances. The GBUAPCD exercises joint jurisdiction over Owens Valley and the CJPA and therefore has authority to adopt and implement controls in both areas. Pursuant to this authority, the GBUAPCD has in fact adopted and implemented control measures to address the PM–10 contribution to the CJPA from Owens Valley. See section C above for a detailed discussion of these control measures.

Finally, EPA notes that in 1999 (See 64 FR 34173 and 64 FR 48305), EPA found that the motor vehicle emissions contribution in Owens Valley itself was insignificant. This earlier finding for Owens Valley supports the proposed finding for the CJPA—if motor vehicles are not a significant contributor to the PM–10 emissions problem in Owens Valley itself, where the primary source of PM–10 emissions is located, then it is reasonable to conclude that motor vehicle emissions are also not a significant contributor to the PM–10 emissions problem in neighboring CJPA.

In the context of these unique factual circumstances, EPA is proposing to find that motor vehicle emissions are an insignificant contributor to the PM–10 problem in the CJPA. Consideration of the other factors specified in EPA's regulations supports this proposed finding and is described below.

Current Air Quality as Determined by PM–10 Monitoring Data

Current air quality as determined by PM–10 monitoring data show that the CJPA attains the PM–10 standard. As discussed in section A above, for PM–10 in the CJPA, EPA has reviewed the ambient air quality data and determined that the CJPA has attained the PM–10 standard through 2009 and continues to attain to date. See 75 FR 13710 and 75 FR 27944.

Absence of SIP Motor Vehicle Control Measures

There are no local PM–10 motor vehicle control measures for the CJPA. With the exception of GBUAPCD Rule 401—Fugitive Dust, that may apply to area sources such as unpaved roads, there are no specific CJPA only PM–10 motor vehicle control measures. Of course, national and state-wide motor vehicle emission controls may apply, but they are not GBUAPCD adopted and CJPA specific motor vehicle control measures. Furthermore, these state-wide and national emission control measures would contribute to reductions in motor vehicle related PM–10 emissions in the CJPA.

Historical Trends and Future Projections of the Growth of Motor Vehicle Related PM–10 Emissions

Finally, historical trends and future projections of the growth of motor vehicle related PM–10 emissions suggest that motor vehicle related PM–10 emissions are not likely to increase, and therefore not likely to cause or contribute to violations of the PM–10 standard. The CJPA is within a sparsely populated area of Inyo County, California. An estimated 102 people live in two communities of Pearsonville and Homewood Canyon. These two communities are located at the southern end of the CJPA, approximately 25 miles apart and separated by the China Lake NAWS. Commuters from these communities most likely travel south out of the CJPA to Ridgecrest, a small

[12] Depending on the year, the emissions from the Owens Valley area are estimated to be anywhere from approximately 8,000 to 47,000 tons per year (past actual estimates are anywhere from 10,000 to 86,000 tons per year). *See* 2010 Plan, Figure 4. The CJPA PM–10 emissions of 269.74 tons per year (converted from the 1,478 pounds per day estimate found in the 2010 Plan, Table 4) are approximately 3% when compared to the lowest estimate emissions level (8,000 tons per year) for the Owens Valley area.

community of approximately 27,600 people.[13] According to US Census figures, in the period 1990 to 2008, Inyo County population did not increase, but dropped 4.5%. (See 2010 Plan, Section 4.4, pages 10–11.) Within the CJPA, almost all of the land, 98.5%, is controlled by the federal government: the Department of Defense through the China Lake NAWS controls 63%; the Department of the Interior through the Bureau of Land Management (BLM) and the Forest Service controls 32.6% and 2.9%, respectively, with just over twelve percent (12.2%) of BLM land designated as wilderness.[14] All of these entities restrict access, development, or both within the lands they control. In summary, given a sparse population, historically declining or no population growth, the absence of any significant commutershed in the CJPA, limited land ownership, and restricted access or development, PM–10 related motor vehicle emissions are not expected to increase in the CJPA to the point where a violation would occur.

EPA Proposal for Transportation Conformity and MVEBs in the CJPA

Given the factors discussed above, we are proposing to find that motor vehicle-related PM–10 emissions are insignificant contributors to the CJPA's PM–10 nonattainment problem and that it would be unreasonable to expect that motor vehicle related PM–10 emissions would grow enough within the CJPA to threaten the PM–10 standard. If this proposal is finalized, a regional emissions analysis would not be required for PM–10 in any future conformity determination in the CJPA.

Given that the CJPA is an isolated rural area, if EPA takes final action finding the motor vehicle emissions PM–10 contribution is insignificant, a conformity determination would be necessary only in the case where a transportation project needs federal funding or approval. Even with an insignificance finding, such a conformity determination would need to include a hot-spot analysis, if the project is one of the types found in 40 CFR 93.123(b).

IV. Proposed Actions

Based on our review of the 2010 Plan submitted by the State, air quality monitoring data, and other relevant materials, EPA believes the State has addressed all the necessary requirements for the redesignation of the CJPA to attainment, pursuant to CAA sections 107(d)(3)(E) and 175A. Assuming that California adopts the maintenance plan and associated controls as they are currently drafted, EPA is therefore proposing to redesignate the CJPA to attainment for the PM–10 NAAQS. EPA also proposes to approve the maintenance plan for CJPA which includes the GBUAPCD Board Order #080128–01 as a SIP revision. As discussed above the Board Order includes all of the control measures in the 1998 Owens Valley SIP, and the 2003 and 2008 SIP revisions for Owens Valley. EPA is also proposing to approve the emissions inventory submitted with the maintenance plan as meeting the requirements of section 172(c)(3). If the State substantially revises the submitted control measures or maintenance plan from the versions proposed by the State and reviewed here, this will result in the need for additional proposed rulemaking on the maintenance plan and redesignation. Finally, EPA is proposing to find the contribution of motor vehicles to the area's PM–10 problem insignificant, and if this insignificance finding is finalized, the area would not have to complete a regional emissions analysis for any transportation conformity determinations necessary in the CJPA.

V. Statutory and Executive Order Reviews

Under the CAA, redesignation of an area to attainment and the accompanying approval of a maintenance plan under section 107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those imposed by State law. A redesignation to attainment does not in and of itself create any new requirements, but rather results in the applicability of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For these reasons, these actions:

- Are not "significant regulatory actions" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Are certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Do not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Are not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Are not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Are not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Do not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Authority: 42 U.S.C. 7401 *et seq.*

[13] U.S. Census Bureau, 2006–2008 American Community Survey.

[14] Data source is *http://www.nationalatlas.gov; http://nationalatlas.gov/mld/fedlandp.html;* shape file from Federal Lands of the United States map.

Dated: June 18, 2010.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2010–15453 Filed 6–23–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 87

[EPA–HQ–OAR–2007–0294; FRL–9167–4]

RIN 2060–AP79

Advance Notice of Proposed Rulemaking on Lead Emissions From Piston-Engine Aircraft Using Leaded Aviation Gasoline; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: EPA is announcing a 60-day extension of the public comment period for the Advance Notice of Proposed Rulemaking on Lead Emissions From Piston-Engine Aircraft Using Leaded Aviation Gasoline (hereinafter referred to as the ANPR). EPA published this ANPR, which included a request for comment, in the **Federal Register** on April 28, 2010. The public comment period was to end on June 28, 2010 (60 days after its publication in the **Federal Register**). This document extends the comment period an additional 60 days until August 27, 2010. This extension of the comment period is provided to allow the public additional time to provide comment on the ANPR.

DATES: The comment period for the ANPR published April 28, 2010 (75 FR 22440) is extended. Written comments must be received on or before August 27, 2010.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2007–0294, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: a-and-r-docket@epa.gov.*
- *Fax:* (202) 566–9744.
- *Mail:* Environmental Protection Agency, Mail Code: 6102T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include two copies.
- *Hand Delivery:* EPA Docket Center (Air Docket), U.S. Environmental Protection Agency, EPA West Building, 1301 Constitution Avenue, NW., Room: 3334 Mail Code: 2822T, Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2007–0294. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.* For additional instructions on submitting comments, please refer to the **SUPPLEMENTARY INFORMATION** section of the advance notice of proposed rulemaking document.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the EPA Docket Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Avenue, NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

How can I get copies of this document, the advance notice of proposed rulemaking, and other related information?

The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2007–0294. The EPA has also developed a Web site for aviation, including the ANPR, at: *http://www.epa.gov/otaq/aviation.htm.* Please refer to the ANPR for detailed information on accessing information related to this notice.

FOR FURTHER INFORMATION CONTACT: Marion Hoyer, Assessment and Standards Division, Office of Transportation and Air Quality, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: (734) 214–4513; fax number: (734) 214–4821; e-mail address: *hoyer.marion@epa.gov.*

SUPPLEMENTARY INFORMATION:

Background: In the ANPR, EPA described and invited comment from all interested parties on the data available for evaluating lead emissions, ambient concentrations and potential exposure to lead from the use of leaded aviation gasoline (avgas) in piston-engine powered aircraft. The ANPR is one of the steps EPA has taken in response to a petition submitted by Friends of the Earth (FOE) requesting that EPA find endangerment from and regulate lead emitted by piston-engine aircraft, or if insufficient information exists, to commence a study. In addition to describing and inviting comment on the current data, the ANPR also describes considerations regarding emission engine standards and requests comment on approaches for transitioning the piston-engine fleet to unleaded avgas.

Extension of Comment Period: EPA received requests for an extension of the ANPR comment period that are available in the docket for this rule (EPA–HQ–OAR–2007–0294). After considering the requests, EPA has determined that a 60-day extension of the comment period would provide the public adequate time to provide meaningful comment on the ANPR. Accordingly, the public comment period for the ANPR is extended until August 27, 2010. EPA does not anticipate any further extension of the comment period at this time.

Dated: June 18, 2010.

Gina McCarthy,

Assistant Administrator, Office of Air and Radiation.

[FR Doc. 2010–15340 Filed 6–23–10; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R4-ES-2010-0027]
[MO 92210-0-0008-B2]

RIN 1018-AV85

Endangered and Threatened Wildlife and Plants; Listing the Cumberland Darter, Rush Darter, Yellowcheek Darter, Chucky Madtom, and Laurel Dace as Endangered Throughout Their Ranges

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; request for public comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list the Cumberland darter (*Etheostoma susanae*), rush darter (*Etheostoma phytophilum*), yellowcheek darter (*Etheostoma moorei*), chucky madtom (*Noturus crypticus*), and laurel dace (*Phoxinus saylori*) as endangered under the Endangered Species Act of 1973, as amended (Act). If we finalize this rule as proposed, it would extend the Act's protections to these species throughout their ranges, including, Cumberland darter in Kentucky and Tennessee, rush darter in Alabama, yellowcheek darter in Arkansas, and chucky madtom and laurel dace in Tennessee. We have determined that critical habitat for these species is prudent, but not determinable at this time.

DATES: We will consider comments we receive on or before August 23, 2010. We must receive requests for public hearings, in writing, at the address shown in the **ADDRESSES** section by August 9, 2010.

ADDRESSES: You may submit comments by one of the following methods:

Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

U.S. mail or hand-delivery: Public Comments Processing, Attn: [Docket No. FWS-R4-ES-2010-0027]; Division of Policy and Directives Management, U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, Suite 222, Arlington, VA 22203.

We will not accept e-mail or faxes. We will post all comments on *http://www.regulations.gov*. This generally means that we will post any personal information you provide us (see the **Request for Public Comments** section below for more information).

FOR FURTHER INFORMATION CONTACT: For information regarding the Cumberland darter, contact Lee Andrews, Field Supervisor, U.S. Fish and Wildlife Service, Kentucky Ecological Services Field Office, J.C. Watts Federal Building, 330 W. Broadway Rm. 265, Frankfort, KY 40601; telephone 502-695-0468; facsimile 502-695-1024. For information regarding the rush darter, contact Stephen Ricks, Field Supervisor, U.S. Fish and Wildlife Service, Mississippi Ecological Services Field Office, 6578 Dogwood View Parkway, Suite A, Jackson, MI 39213; telephone 601-965-4900; facsimile 601-965-4340 or Bill Pearson, Field Supervisor, U.S. Fish and Wildlife Service, Alabama Ecological Services Field Office, 1208-B Main Street, Daphne AL 36526; telephone 251-441-5181; fax 251-441-6222. For information regarding the yellowcheek darter, contact Mark Sattelberg, Field Supervisor, U.S. Fish and Wildlife Service, Arkansas Ecological Services Field Office, 110 South Amity Road, Suite 300, Conway, AR 72032; telephone 501-513-4470; facsimile 501-513-4480. For information regarding the chucky madtom or laurel dace, contact Mary Jennings, Field Supervisor, U.S. Fish and Wildlife Service, Tennessee Ecological Services Field Office, 446 Neal Street, Cookeville, TN 38501; telephone 931-528-6481; facsimile 931-528-7075. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800-877-8339.

SUPPLEMENTARY INFORMATION:

Request for Public Comments

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and as accurate and effective as possible. Therefore, we request comments or information from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule. We particularly seek comments concerning:

(1) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to these species and regulations that may be addressing those threats;

(2) Additional information concerning the ranges, distribution, and population size of these species, including the locations of any additional populations of the species;

(3) Any additional information on the biological or ecological requirements of the species;

(4) Current or planned activities in the areas occupied by the species and possible impacts of these activities on the species and their habitat;

(5) Potential effects of climate change on the species and their habitats;

(6) The reasons why areas should or should not be designated as critical habitat as provided by section 4 of the Act (16 U.S.C. 1531, *et seq.*), including whether the benefits of designation would outweigh threats to the species that designation could cause (e.g., exacerbation of existing threats, such as overcollection), such that the designation of critical habitat is prudent; and .

(7) Specific information on:

- What areas contain physical and biological features essential for the conservation of the species;
- What areas are essential to the conservation of the species; and
- Special management considerations or protection that proposed critical habitat may require.

Please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is a threatened or endangered species mush be made "solely on the basis of the best scientific and commercial data available."

You may submit your comments and materials concerning this proposed rule by one of the methods listed in the **ADDRESSES** section. We will not accept comments sent by e-mail or fax or to an address not listed in the **ADDRESSES** section.

We will post your entire comment, including your personal identifying information, on *http://www.regulations.gov*. If you provide personal identifying information in your hard copy comments, such as your street address, phone number, or e-mail address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov*. Please include sufficient information with your comments to allow us to verify any scientific or commercial information you include.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov*, or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Tennessee Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT** section).

Background

Species Information

Cumberland darter

The Cumberland darter, *Etheostoma susanae* (Jordan and Swain), is a medium-sized member of the fish tribe Etheostomatini (Family Percidae) that reaches over 5.5 centimeters (cm) (2 inches (in)) standard length (SL) (SL, length from tip of snout to start of the caudal peduncle (slender region extending from behind the anal fin to the base of the caudal fin)) (Etnier and Starnes 1993, pp. 512). The species has a straw-yellow background body color with brown markings that form six evenly spaced dorsal (back) saddles and a series of X-, C-, or W-shaped markings on its sides (Etnier and Starnes 1993, p. 510). During spawning season, the overall body color of breeding males darkens, and the side markings become obscure or appear as a series of blotches (Etnier and Starnes 1993, p. 510).

The Cumberland darter was first reported as *Boleosoma susanae* by Jordan and Swain (1883, pp. 249–250) from tributaries of the Clear Fork of the Cumberland River, Kentucky. Subsequent studies by Kuhne (1939, p. 92) and Cole (1967, p. 29) formerly recognized the taxon as a subspecies (*Etheostoma nigrum susanae*) of *E. n. nigrum* (Johnny darter). Starnes and Starnes (1979, p. 427) clarified the subspecific status of the Cumberland darter, differentiating it from the Johnny darter by several diagnostic characteristics. Strange (1994, p. 14; 1998, p. 101) recommended that *E. n. susanae* be elevated to specific status based on the results of mitochondrial DNA analyses of *E. n. susanae* and *E. n. nigrum*. The Cumberland darter was recognized as a valid species, *E. susanae* (Cumberland darter), by Nelson *et al.* (2004, p. 233) based on the work of Strange (1994, p. 14; 1998, p. 101) and a personal communication with W. C. Starnes (May 2000), who suggested the common name.

The Cumberland darter inhabits pools or shallow runs of low to moderate gradient sections of streams with stable sand, silt, or sand-covered bedrock substrates (O'Bara 1988, pp. 10–11; O'Bara 1991, p. 10; Thomas 2007, p. 4). Thomas (2007, p. 4) did not encounter the species in high-gradient sections of streams or areas dominated by cobble or boulder substrates. Thomas (2007, p. 4) reported that streams inhabited by Cumberland darters were second to fourth order, with widths ranging from 4 to 9 meters (m) (11 to 30 feet (ft)) and depths ranging from 20 to 76 cm (8 to 30 in).

Little is known regarding the reproductive habits of the Cumberland darter. Thomas (2007, p. 4) reported the collection of males in breeding condition in April and May, with water temperatures ranging from 15 to 18° Celsius (C) (59 to 64° Fahrenheit (F)). Extensive searches by Thomas (2007, p. 4) produced no evidence of nests or eggs at these sites. Species commonly associated with the Cumberland darter during surveys by Thomas (2007, pp. 4–5) were creek chub (*Semotilus atromaculatus*), northern hogsucker (*Hypentelium nigricans),* stripetail darter *(Etheostoma kennicotti),* and Cumberland arrow darter *(Etheostoma sagitta sagitta*). Thomas (2007, p. 5) collected individuals of the Federally threatened blackside dace, *Phoxinus cumberlandensis*, from three streams that also supported Cumberland darters.

The Cumberland darter is endemic to the upper Cumberland River system above Cumberland Falls in Kentucky and Tennessee (O'Bara 1988, p. 1; O'Bara 1991, p. 9; Etnier and Starnes 1993, p. 511). The earliest known collections of the species were made by Jordan and Swain (1883, pp. 249–250), who recorded it as abundant in tributaries of Clear Fork of the Cumberland River, Kentucky. The species was later reported from Gum Fork, Scott County, Tennessee, by Shoup and Peyton (1940, p. 11), and seven additional tributaries of the Cumberland River by Burr and Warren (1986, p. 310). More exhaustive surveys by O'Bara (1988, p. 6; 1991, pp. 9–10) and Laudermilk and Cicerello (1998; pp. 83–233, 303–408) determined that the Cumberland darter was restricted to short reaches of 20 small streams (23 sites) in the upper Cumberland River system in Whitley and McCreary Counties, Kentucky, and Campbell and Scott Counties, Tennessee. These studies suggested the extirpation of the species from Little Wolf Creek, Whitley County, Kentucky, and Gum Fork, Scott County, Tennessee. Preliminary reports of disjunct populations in the Poor Fork Cumberland River and Martins Fork in Letcher and Harlan Counties, Kentucky (Starnes and Starnes 1979, p. 427; O'Bara 1988, p. 6; O'Bara 1991, pp. 9–10), were evaluated genetically and determined to be the Johnny darter (Strange 1998, p. 101). Thomas (2007, p. 3) provided the most recent information on status and distribution of the species through completion of a range-wide status assessment in the upper Cumberland River drainage in Kentucky. Between June 2005 and April 2007, a total of 47 sites were sampled qualitatively in the upper Cumberland River drainage. All Kentucky sites with historic records were surveyed (20 sites), as well as 27 others having potentially suitable habitat. Surveys by Thomas (2007, p. 3) produced a total of 51 specimens from 13 localities (12 streams). Only one of the localities represented a new occurrence record for the species.

Currently, the Cumberland darter is known from 14 localities in a total of 12 streams in Kentucky (McCreary and Whitley Counties) and Tennessee (Campbell and Scott Counties). All 14 extant occurrences of the Cumberland darter are restricted to short stream reaches, with the majority believed to be restricted to less than 1.6 kilometers (km) (1 mile (mi)) of stream (O'Bara 1991, pp. 9–10; Thomas 2007, p. 3). These occurrences are thought to form six population clusters (Bunches Creek, Indian Creek, Marsh Creek, Jellico Creek, Clear Fork, and Youngs Creek), which are geographically separated from one another by an average distance of 30.5 stream km (19 mi) (O'Bara 1988, p. 12; O'Bara 1991, p. 10; Thomas 2007, p. 3). Based on collection efforts by O'Bara (1991, pp. 9–10), Laudermilk and Cicerello (1998, pp. 83–233, 303–408), and Thomas (2007, p. 3), the species appears to be extirpated from 11 historic collection sites and a total of 9 streams: Cumberland River mainstem, near mouth of Bunches Creek and Cumberland Falls (Whitley County); Sanders Creek (Whitley County); Brier Creek (Whitley County); Kilburn Fork of Indian Creek (McCreary County); Bridge Fork (McCreary County); Marsh Creek, near mouth of Big Branch and Caddell Branch (McCreary County); Cal Creek (McCreary County), Little Wolf Creek (Whitley County); and Gum Fork (Scott County). No population estimates or status trends are available for the Cumberland darter; however, survey results by Thomas (2007, p. 3) suggest that the species is uncommon or occurs in low densities across its range (Thomas (2007, p. 3).

The Cumberland darter is ranked by the Kentucky State Nature Preserves Commission (2009, p. 38) as a G1G2S1 species: critically imperiled or imperiled globally and critically imperiled in Kentucky. The Kentucky Department of Fish and Wildlife Resources State Wildlife Action Plan

identified the Cumberland darter as a species of Greatest Conservation Need (KDFWR 2005, p. 2.2.2). The plan identified several top conservation actions for the Cumberland darter and other species in its Aquatic Guild (Upland Headwater Streams in Pools): acquisition or conservation easements for critical habitat, development of financial incentives to protect riparian corridors, development and implementation of best management practices, and restoration of degraded habitats through various State and Federal programs.

Rush Darter

The rush darter (*Etheostoma phytophilum*), a medium-sized darter in the subgenus *Fuscatelum*, was described by Bart and Taylor in 1999 (pp. 27–33). The average size of the rush darter is 5 cm (2 in) SL (Bart and Taylor 1999, p. 28; Johnston and Kleiner 2001, p. 3). The rush darter is closely related to the goldstripe darter (*Etheostoma parvipinne*), a drab-colored species with a thin golden stripe along the lateral line (canal along the side of a fish with sensory capabilities) that is surrounded by heavily mottled or stippled sides (Shaw 1996, p. 85). However, the distinct golden stripe characteristic of goldstripe darters is not well developed in rush darters (Bart and Taylor 1999, p. 29). Also, the brown pigment on the sides of the rush darter is usually not as intense as in the goldstripe darter. Other characteristics of the rush darter are described in Bart and Taylor (1999, p. 28).

Rush darters have been collected from various habitats (Stiles and Mills 2008, pp. 1–4; Bart 2002, p. 1; Johnston and Kleiner 2001, pp. 3–4; Stiles and Blanchard 2001, pp. 1–4; Bart and Taylor 1999, p. 32), including root masses of emergent vegetation along the margins of spring-fed streams in very shallow, clear, cool, and flowing water; and from both small clumps and dense stands of bur reed (*Sparganium* sp.), coontail (*Ceratophyllum* sp.), watercress (*Nasturtium officinale*), and rush (*Juncus* sp.) in streams with substrates of silt, sand, sand and silt, muck and sand or some gravel with sand, and bedrock. Rush darters appear to prefer springs and spring-fed reaches of relatively low-gradient small streams which are generally influenced by springs (Stiles and Mills 2008, pp. 1–4; Fluker *et al.* 2007, p. 1; Bart 2002, p. 1; Johnston and Kleiner 2001, pp. 3–4; Stiles and Blanchard 2001, pp. 1–4; Bart and Taylor 1999, p. 32). Rush darters have also been collected in wetland pools (Stiles and Mills 2008; pp. 2–3). Water depth at collection sites ranged from 3.0 cm to 0.5 m (0.1 ft to 1.6 ft), with moderate water velocity in riffles and no flow or low flow in pools. Rush darters have not been found in higher gradient streams with bedrock substrates and sparse vegetation (Stiles and Mills 2008, pp. 1–4; Bart 2002, p. 1; Johnston and Kleiner 2001, pp. 3–4; Stiles and Blanchard 2001, pp. 1–4; Bart and Taylor 1999, p. 32).

Stiles and Mills (2008, p. 2) found gravid rush darter females in February and fry (newly hatched larval fish) in late April from a wetland pool in the Mill Creek watershed (Winston County, Alabama). These pools act as nursery areas for the fry (Stiles and Mills 2008, p. 5). Even though the life history of the rush darter is poorly known, it is likely similar to the closely related goldstripe darter. Spawning of the goldstripe darter in Alabama occurs from mid March through June (Mettee *et al.* 1996, p. 655). Goldstripe larvae reared in captivity avoid downstream drift (Conservation Fisheries, Inc., 2005, p. 7). This behavior alteration may inhibit dispersal capabilities between isolated suitable habitat patches, and may reduce the success of captively bred individuals in the wild. Preferred food items for the goldstripe darter include midges, mayflies, blackflies, beetles, and microcrustaceans (Mettee *et al.* 1996, p. 655). The life span of the goldstripe darter is estimated to be 2 to 3 years.

The rush darter currently has a restricted distribution (Johnston and Kleiner 2001, p. 1). All rush darter populations are located above the Fall Line (the inland boundary of the Coastal Plain physiographic region) and other "highland regions" where topography and elevation changes are observed presenting a barrier for fish movement (Boshung and Mayden 2004, p. 18)) in the Tombigbee–Black Warrior drainage (Warren *et al.* 2000, pp. 9, 10, 24), in portions of the Appalachian Plateau, and Valley and Ridge physiographic provinces of Alabama. The closely related goldstripe darter in Alabama occurs essentially below the Fall Line in all major systems except the Coosa system (Boshung and Mayden 2004, p. 550). Reports of goldstripe darters from the 1960s and 1970s in Winston and Jefferson Counties, Alabama (Caldwell 1965, pp. 13–14; Barclay 1971, p. 38; Dycus and Howell 1974, pp. 21–24; Mettee *et al.* 1989, pp. 13, 61, 64), which are above the Fall Line, were made prior to the description of the rush darter, but are now considered to be rush darters (Kuhajda 2008, pers. comm.).

Historically, rush darters have been found in three distinct watersheds in Alabama: Doe Branch, Wildcat Branch, and Mill Creek of the Clear Creek drainage in Winston County; an unnamed spring run of Beaver Creek and from Penny Springs of the Turkey Creek drainage in Jefferson County; and Cove Spring (Little Cove Creek system) and Bristow Creek of the Locust Fork drainage in Etowah County.

Currently, the three rush darter populations occur in the same watersheds but in a more limited distribution. One population is located in Wildcat Branch and Mill Creek in the Clear Creek drainage in Winston County (Johnston and Kleiner 2001, p. 4); the second is located in an unnamed spring run to Beaver Creek and in Penny Springs in the Turkey Creek drainage in Jefferson County (Stiles and Blanchard 2001, p. 2); and the third is in the Little Cove Creek drainage population. The Little Cove Creek population in Etowah County was known from only a single specimen collected in Cove Spring in 1975 (Bart and Taylor 1999, p. 28) and one specimen from Bristow Creek collected in 1997 (Bart 2002, p. 7). Kuhajda (2008, pers. comm.) discovered a single specimen of the species in 2005, at the confluence of the Cove Spring run where it drains into an unnamed swamp.

Rush darter populations are separated from each other geographically, and individual rush darters are only sporadically collected at a particular site within their range. Where it occurs, the rush darter is apparently an uncommon species that is usually collected in low numbers (Bart and Taylor 1999, p. 32). Since 1969, approximately 100 rush darters have been collected or captured and released within the species' range (compiled from Bart and Taylor 1999, pp. 31–32; Johnston and Kleiner 2001, pp. 2–4; Stiles and Blanchard 2001, pp. 1–4; Johnston 2003, pp.1-3; P. Rakes 2010, pers.comm.); however, there are no population estimates at this time.

Cumulatively, the rush darter is only known from localized collection sites within approximately 14 km (9 mi) of streams in the Clear Creek, Little Cove and Bristow Creek, and Turkey Creek drainages in Winston, Etowah, and Jefferson Counties, respectively. Currently, about 3 km (2 mi) of stream, or about 22 percent of the rush darter's known range, is not occupied, which may be due to non-point source pollution (e.g., sedimentation and chemicals) from agriculture, urbanization, and road construction and maintenance.

Within the Clear Creek drainage, the rush darter has been collected in Wildcat Branch, Mill Creek, and Doe Creek, which represents about 13 km (8 mi) of stream or about 94 percent of the species' total cumulative range. Recent

surveys (Stiles and Mills 2008, pp. 1–4; Johnston and Kleiner 2001, p. 3) have documented the absence of the rush darter in Doe Creek, possibly indicating a reduction of the species' known range within the Clear Creek drainage by about 3 km (2 mi) of stream or 22 percent. Rush darters were collected in October 2005 and again in June 2008 and 2009 in the Little Cove Creek drainage (Cove Spring run), a first since 1975, despite sporadic surveys over the last 30 years. This rediscovery of the species confirms the continued existence of the species in Etowah County and Cove Spring. However, the Little Cove Creek drainage constitutes an increase of only 0.05 km (0.02 mi) of occupied stream habitat or a 1.6 percent addition to the total range of the species. No collections of the species have occurred at Bristow Creek since 1997. Bristow Creek has since been channelized (straightened and deepened to increase water velocity). In the Turkey Creek drainage, rush darters have been collected sporadically within Penny Springs and at the type locality for the species (an unnamed spring run in Jefferson County, Alabama) (Bart and Taylor 1999, pp. 28, 33). This area contains about 0.5 km (0.3 mi) of occupied stream habitat or approximately 4 percent of the rush darter's total range.

The rush darter is ranked by the Alabama Department of Conservation and Natural Resources (2005) as a P1G1S1 species signifying its rarity in Alabama and its status as critically imperiled globally. It is also considered a species of Greatest Conservation Need (GCN) by the State. The rush darter has a High Priority Conservation Actions Needed and Key Partnership Opportunities ranking of "CA 6," the highest of any fish species listed. The plan states that the species consists of disjoint populations and information is needed to determine genetic structuring within the populations. Conservation Actions for the species may require population augmentation and/or reintroduction of the species to suitable habitats to maintain viability.

Yellowcheek Darter

The yellowcheek darter (*Etheostoma moorei*) is a small and compressed fish which attains a maximum SL of about 64 mm (2.5 in), and has a moderately sharp snout, deep body, and deep caudal peduncle (Raney and Suttkus 1964, p. 130). The back and sides are grayish brown, often with darker brown saddles and lateral bars. Breeding males are brightly colored with a bright blue or brilliant turquoise breast, and throat and light green belly, while breeding females possess orange and red-orange spots but are not brightly colored (Robison and Buchanan 1988, pp. 427–429). First collected in 1959 from the Devils Fork Little Red River, Cleburne County, Arkansas, this species was eventually described by Raney and Suttkus in 1964, using 228 specimens from the Middle, South, and Devils Forks of the Little Red River (Devils Fork, Turkey Fork, and Beech Fork represent one stream with three different names and are subsequently referred to in this proposed rule as "Devils Fork"). Wood (1996, p. 305) verified the taxonomic status of the yellowcheek darter within the subgenus *Nothonotus*. The yellowcheek darter is one of only two members of the subgenus *Nothonotus* known to occur west of the Mississippi River.

The yellowcheek darter inhabits high-gradient headwater tributaries with clear water; permanent flow; moderate to strong riffles; and gravel, rubble, and boulder substrates (Robison and Buchanan 1988, p. 429). Yellowcheek darter prey items include aquatic dipteran larvae, stoneflies, mayflies, and caddisflies (McDaniel 1984, p. 56).

Male and female yellowcheek darters reach sexual maturity at one year of age, and maximum life span is around five years (McDaniel 1984, pp. 25, 76). Spawning occurs from late May through June in the swift to moderately swift portions of riffles, often around or under the largest substrate particles (McDaniel 1984, p. 82), although brooding females have been found at the head of riffles in smaller gravel substrate (Wine *et al.* 2000, p. 3). During non-spawning months, there is a general movement to portions of the riffle with smaller substrate, such as gravel or cobble, and less turbulence (Robison and Harp 1981, p. 3). Weston and Johnson (2005, p. 24) observed that the yellowcheek darter moved very little during a 1–year migration study. It was noted that the yellowcheek darter appears to be a relatively non-mobile species, with 19 of 22 recaptured darters found within 9 meters (29.5 feet) of their original capture position after periods of several months. A number of life history characteristics, including courtship patterns, specific spawning behaviors, egg deposition sites, number of eggs per nest, degree of nest protection by males, and degree of territoriality are unknown at this time; however, researchers have suggested that the yellowcheek darter deposit eggs on the undersides of larger rubble in swift water (McDaniel 1984, p. 82). Wine and Blumenshine (2002, p. 10) noted that during laboratory spawning, female yellowcheek darters bury themselves in fine gravel/sand substrates (often behind large cobble or boulders) with only their heads and caudal fin exposed. A male yellowcheek darter will then position upstream of the buried female and fertilize her eggs as she releases them in a vibrating motion. Clutch size and nest defense behavior were not observed.

The yellowcheek darter is endemic to the Devils, Middle, South, and Archey Forks of the Little Red River and main stem Little Red River in Cleburne, Searcy, Stone, and Van Buren Counties, Arkansas (Robison and Buchanan 1988, p. 429). In 1962, the construction of a dam on the Little Red River to create Greers Ferry Reservoir impounded much of the range of this species, including the lower reaches of Devils Fork, Middle Fork, South Fork, and portions of the main stem Little Red River, thus extirpating the species from these reaches. Yellowcheek darter was also extirpated from the Little Red River downstream of Greers Ferry Reservoir due to cold tailwater releases. The lake flooded optimal habitat for the species, and caused the genetic isolation of populations (McDaniel 1984, p. 1). The yellowcheek darter was known to historically occur in portions of these streams that maintained permanent year-round flows.

In the 1978-81 study by Robison and Harp (1981, pp. 15–16), yellowcheek darter occurred in greatest numbers in the Middle and South Forks of the Little Red River, with populations estimated at 36,000 and 13,500 individuals, respectively, while populations in both Devils Fork and Archey Fork were estimated at approximately 10,000 individuals (Robison and Harp 1981, pp. 5–11). During this study, the four forks of the Little Red River supported an estimated yellowcheek darter population of 60,000 individuals, and the species was considered the most abundant riffle fish present (Robison and Harp 1981, p. 14). Extensive sampling of the first two tributaries of the Little Red River below Greers Ferry Dam (both named Big Creek) failed to find any yellowcheek darters, and no darters were found in immediately adjacent watersheds (Robison and Harp 1981, p. 5).

Two subsequent studies have failed to observe specimens of yellowcheek darter in the Turkey Fork reach of the Devils Fork Little Red River (Wine *et al.* 2000, p. 9; Wine and Blumenshine 2002, p. 11), since four individuals were last collected by Arkansas State University (ASU) researchers in 1999 (Mitchell *et al.* 2002, p. 129). They have been observed downstream within that system in the Beech Fork reach, where flows are more permanent. The reach

downstream of Raccoon Creek is influenced by inundation from Greers Ferry Reservoir and no longer supports yellowcheek darter. The U.S. Army Corps of Engineers channelized approximately 5.6-km (3.5 mi) of the lower Archey and South Forks Little Red River located within the city limits of Clinton, Arkansas, in 1985 for flood control purposes. Yellowcheek darter has not been collected within this 5.6-km (3.5-mi) reach since channelization. The yellowcheek darter otherwise inhabits most of its historical range, although in greatly reduced numbers in the Middle, South, Archey, and Devils Forks of the Little Red River.

While collecting specimens for the 1999 genetic study, ASU researchers discovered that the yellowcheek darter was no longer the most abundant riffle fish and was more difficult to find (Wine *et al.* 2000, p. 2). Because optimal habitat had been destroyed by the creation of Greers Ferry Lake, yellowcheek darters were confined to upper stream reaches with lower summer flow, smaller substrate particle size, and reduced gradient. A thorough status survey conducted in 2000 found the yellowcheek darter in three of four historic forks in greatly reduced numbers (Wine *et al.* 2000, p. 9). Populations in the Middle Fork were estimated at approximately 6,000 individuals, the South Fork at 2,300, and the Archey Fork at 2,000. Yellowcheek darter was not collected from the Devils Fork. Yellowcheek darter was the fifth most abundant riffle fish rangewide, while historically it was the most abundant riffle fish. Fish community composition was similar from 1978-1981 and 2000 studies, but the proportion of yellowcheek darter declined from approximately 28 percent to 6 percent of the overall composition. Fish known to co-exist with yellowcheek darter include the rainbow darter (*E. caeruleum*) and greenside darter (*E. blennioides*), which can use pool habitats during periods of low flow, as evidenced by the collection of these two species from pools during electroshocking activities. Electroshocking has not revealed yellowcheek darter in pools, suggesting perhaps that they are unable to tolerate pool conditions (deep, slow-moving water usually devoid of cobble substrate). An inability to use pools during low flows would make them much more vulnerable to seasonal fluctuations in flows that reduce riffle habitat. As a result, researchers have suggested that yellowcheek darter declines are more likely a species rather than community phenomenon (Wine *et al.* 2000, p. 11).

Weston and Johnson (2005, p. 22) estimated yellowcheek darter populations within the Middle Fork to be between 15,000 and 40,000 individuals, and between 13,000 and 17,000 individuals in the South Fork. Such increases since the status survey done in 2000 would indicate remarkable adaptability to changing environmental conditions. However, it should be noted that estimates were based upon mark/recapture estimates using the Jolly-Seber method which requires high numbers of recaptured specimens for accurate estimations. Recaptures were extremely low during that study; therefore, population estimates were highly variable and confidence in the resulting estimates is low.

The yellowcheek darter is ranked by the Arkansas Natural Heritage Commission (ANHC) (2007, pp. 2–118) as an S1G1 species: extremely rare in Arkansas, and critically imperiled globally. The Arkansas Game and Fish Commission's Arkansas Wildlife Action Plan assigns the yellowcheek darter a score of 100 out of 100, representing a critically imperiled species with declining populations (AGFC 2005, pp. 452–454).

Chucky Madtom

The chucky madtom (*Noturus crypticus*) is a small catfish, with the largest specimen measuring 6.47 cm (2.55 in) SL (Burr *et al.* 2005, p. 795). Burr *et al.* (2005) described the chucky madtom, confirming previous analyses (Burr and Eisenhour 1994), which indicated that the chucky madtom is a unique species, a member of the *Rabida* subgenus (i.e., the "mottled" or "saddled" madtoms), and a member of the *Noturus elegans* species complex (i.e., *N. elegans, N. albater*, and *N. trautmani*) ascribed by Taylor (1969 in Grady and LeGrande 1992). A robust madtom, the chucky madtom body is wide at the pectoral fin origins, greater than 23 percent of the SL. The dorsum (back) contains three dark, nearly black blotches ending abruptly above the lateral midline of the body, with a moderately contrasting, oval, pale saddle anterior to each blotch (Burr *et al.* 2005, p. 795).

The chucky madtom is a rare catfish known from only 15 specimens collected from two Tennessee streams. A lone individual was collected in 1940 from Dunn Creek (a Little Pigeon River tributary) in Sevier County, and 14 specimens have been encountered since 1991 in Little Chucky Creek (a Nolichucky River tributary) in Greene County. Only 3 chucky madtom individuals have been encountered since 2000, 1 in 2000 (Lang *et al.* 2001, p. 2) and 2 in 2004 (Conservation Fisheries, Inc. 2008, unpublished data), despite surveys that have been conducted in both historic localities at least twice a year since 2000 (Rakes and Shute 2004 pp. 2-3; Weber and Layzer 2007, p. 4 Conservation Fisheries, Inc. 2008, unpublished data). In addition, several streams in the Nolichucky, Holston, and French Broad River watersheds of the upper Tennessee River basin, which are similar in size and character to Little Chucky Creek, have been surveyed with no success (Burr and Eisenhour 1994 pp. 1-2; Shute *et al.* 1997 p. 5; Lang *et al.* 2001, pp. 2-3; Rakes and Shute 2004 p.1). Conservation Fisheries, Inc., did not find chucky madtoms in 2007 after attempting new sampling techniques (e.g., PVC "jug" traps) (Conservation Fisheries, Inc. 2008, unpublished data).

Originally, museum specimens collected from the Roaring River (Cumberland River drainage) and from the Paint Rock River system in Alabama (a Tennessee River tributary well downstream of the Nolichucky and Little Pigeon River sites) were first identified and catalogued as *Noturus elegans* and thought to be chucky madtoms. The Roaring River specimens are now considered to be a member of the *N. elegans* group, but have not been assigned to a species. While the specimens from the Paint Rock River system share typical anal ray counts with the chucky madtom, they lack the distinctive cheek characteristics, differ in pelvic ray counts, and are intermediately shaped between the chucky and saddled madtoms, *Noturus fasciatus*, with respect to body width as a proportion of SL (Burr *et al.* 2005, p. 796). Thus, the Little Chucky and Dunn Creek forms are the only forms that are recognized as chucky madtoms.

All of the specimens collected in Little Chucky Creek have been found in stream runs with slow to moderate current over pea gravel, cobble, or slab-rock substrates (Burr and Eisenhour 1994, p. 2). Habitat of these types is sparse in Little Chucky Creek, and the stream affords little loose, rocky cover suitable for madtoms (Shute *et al.* 1997, p. 8). It is notable that intact riparian buffers are present in the locations where chucky madtoms have been found (Shute *et al.* 1997, p. 9).

No studies to determine the life history and behavior of this species have been conducted. While nothing is known specifically about chucky madtom reproductive biology, recruitment, growth and longevity, food habits, or mobility, available

information for other similar members of the *Noturus* group are known. *N. hildebrandi* may reach sexual maturity at one or more years of age (i.e., during their second summer) (Mayden and Walsh 1984, p. 351). Only the largest females of *N. albater* were found to be sexually mature, and males were found to be sexually mature primarily within the second age class (Mayden *et al.* 1980, p. 339). Though, a single large male of the first age class showed evidence of sexual maturity (Mayden *et al.* 1980, p. 339). The breeding season in *N. hildebrandi* and *N. baileyi* was primarily during June through July, though development of breeding condition was initiated as early as April in *N. hildebrandi* and May in *N. baileyi* (Mayden and Walsh 1984, p. 353; Dinkins and Shute 1996, p. 56). Fecundity varied among the species for which data were available; however, it should be noted that fecundity in madtoms is generally lower in comparison to other North American freshwater fishes (Breder and Rosen 1966 *in* Dinkins and Shute 1996, p. 58). Dinkins and Shute (1996, p. 58) commented that for *N. baileyi* the combination of relatively large egg size and high level of parental care given to the fertilized eggs and larvae reduce early mortality and therefore the need to produce a large number of young. Sexual dimorphism (two different forms for male and female individuals) has been observed only in a single pair of specimens of *N. baileyi* collected during the month of May; the male of this pair had swollen lips and enlarged mandibulae (lower jaw) muscles behind the eyes, and the female had a distended abdomen (Burr *et al.* 2005, p. 795).

Both *Noturus baileyi* and *N. elegans* were found to nest under flat rocks at or near the head of riffles (Dinkins and Shute 1996, p. 56; Burr and Dimmick 1981, p. 116). Shallow pools were also used by *N. baileyi*, which was observed to select rocks of larger dimension for nesting than were used for shelter during other times of year (Dinkins and Shute 1996, p. 56). Single madtoms were found to guard nests in *N. baileyi* and *N. elegans*, behavior also exhibited by *N. albater* and *N. hildebrandi* (Dinkins and Shute 1996, p. 56; Burr and Dimmick 1981, p. 116; Mayden *et al.* 1980, p. 337; Mayden and Walsh 1984, p. 357). Males of these species were the nest guardians and many were found to have empty stomachs suggesting that they do not feed during nest guarding, which can last as long as 3 weeks.

Conservation Fisheries, Inc., had one male chucky madtom in captivity from 2004 through 2008. However, based on information from other members of this genus for which longevity data are available, *Noturus hildebrandi* and *N. baileyi*, it is unlikely that chucky madtoms can survive this long in the wild. The shorter lived of these, *N. hildebrandi* reached a maximum age of 18 months, though most individuals lived little more than 12 months, dying soon after reproducing (Mayden and Walsh 1984, p. 351). Based on length-frequency distributions, *N. baileyi* exhibited a lifespan of 2 years, with two cohorts present in a given year (Dinkins and Shute 1996, p. 53). Collection of two age classes together provided evidence that life expectancy exceeds 1 year in *N. stanauli* (Etnier and Jenkins 1980, p. 20). *Noturus albater* lives as long as 3 years (Mayden *et al.* 1980, p. 337).

Invertebrate taxa form the primary food base for madtoms. Chironomid (midge), trichopteran (caddisfly), plecopteran (stonefly), and ephemeropteran (mayfly) larvae were frequently encountered in stomach contents of *Noturus hildebrandi* (Mayden and Walsh 1984, p. 339). In *N. baileyi*, ephemeropteran nymphs comprised 70.7 percent of stomach contents analyzed, dipterans (flies, mosquitoes, midges, and gnats) 2.4 percent, trichopterans 4.4 percent, and plecopterans 1.0 percent (Dinkins and Shute 1996, p. 61). Significant daytime feeding was observed in *N. baileyi*.

The only data on mobility were for *Noturus baileyi*, which were found underneath slabrocks in swift to moderate current during May to early November. Habitat use shifted to shallow pools over the course of a 1–week period, coinciding with a drop in water temperature to 7 or 8° C (45 to 46 ° F), and persisted from early November to May (Dinkins and Shute 1996, p. 50).

The current range of the chucky madtom is believed to be restricted to an approximately 3-km (1.8-mi) reach of Little Chucky Creek in Greene County, Tennessee. Because this species was also collected from Dunn Creek, a stream that is in a different watershed and physiographic province than Little Chucky Creek, it is likely that the historic range of the chucky madtom encompassed a wider area in the Ridge and Valley and the Blue Ridge physiographic provinces in Tennessee than is demonstrated by its current distribution. A survey for the chucky madtom in Dunn Creek in 1996 was not successful at locating the species (Shute *et al.* 1997, p. 8). The Dunn Creek population may be extirpated (Shute *et al.* 1997, p. 6; Burr *et al.* 2005, p. 797), because adequate habitat and a diverse fish community were present at the time of the surveys, but no chucky madtoms were found. There are no population size estimates or status trends for the chucky madtom due to low numbers and only sporadic collections of specimens.

The chucky madtom is ranked by the Tennessee Natural Heritage Program (Withers 2009, p. 58) as an S1G1 species: extremely rare in Tennessee, and critically imperiled globally. In the Tennessee Comprehensive Wildlife Conservation Strategy (CWCS), species of Greatest Conservation Need (GCN) were selected based on their Global imperilment (G1-G3; critically imperiled globally—very rare or restricted throughout their range), knowledge of declining trends or vulnerability, or due to significance of an otherwise wide-ranging species (TWRA 2005, p. 36). Species of GCN were further prioritized into three different tiers to distinguish their status within the State and to determine conservation funding availability. The CWCS designated the chucky madtom as a Tier 1 GCN species in the State, representing species defined as wildlife (amphibians, birds, fish, mammals, reptiles, crustaceans, and mollusks) under Tennessee Code Annotated 70-8-101, and excluding Federally listed species (TWRA 2005, p. 44, 49). Tier 1 species were the primary focus of the Tennessee CWCS (TWRA 2005, p. 44).

Laurel Dace

The laurel dace (*Phoxinus saylori*) has two continuous black lateral stripes and black pigment covering the breast and underside of the head of nuptial (breeding) males (Skelton 2001, p. 120). While the belly, breast, and lower half of the head are typically a whitish-silvery color, at any time of the year laurel dace may develop red coloration below the lateral stripe that extends from the base of the pectoral fins to the base of the caudal fin (Skelton 2001, p. 121).

Nuptial males often acquire brilliant coloration during the breeding season, as the two lateral stripes, breast, and underside of head turn intensely black and the entire ventral (lower/abdominal) portion of the body, contiguous with the lower black stripe and black breast, becomes an intense scarlet color. All of the fins acquire a yellow color, which is most intense in the paired fins and less intense in the dorsal, anal, and caudal fins. Females also develop most of these colors, though of lesser intensity (Skelton 2001, p. 121). Broadly rounded pectoral fins of males are easily discerned from the broadly pointed fins of females at any time during the year. The maximum SL

observed is 5.1 cm (2 in) (Skelton 2001, p. 124).

Laurel dace have been most often collected from pools or slow runs from undercut banks or beneath slab boulders, typically in first or second order, clear, cool (maximum temperature 26° C or 78.8° F) streams. Substrates in streams where laurel dace are found typically consist of a mixture of cobble, rubble, and boulders, and the streams tend to have a dense riparian zone consisting largely of mountain laurel (Skelton 2001, pp. 125–126).

Skelton (2001, p. 126) reported having collected nuptial individuals from late March until mid-June, though Call (Call 2004, pers. obs.) observed males in waning nuptial color during surveys on July 22, 2004. Laurel dace may be a spawning nest associate where syntopic (sharing the same habitat) with nest-building minnow species, as has been documented in *Phoxinus cumberlandensis* (Starnes and Starnes 1981, p. 366). Soddy Creek is the only location in which Skelton (2001, p. 126) has collected a nest-building minnow with laurel dace. Skelton (2001, p. 126) reports finding as many as three year classes in some collections of laurel dace, though young-of-year fish are uncommon in collections. Observations of three year classes indicate that laurel dace live as long as 3 years.

Skelton (2001, p. 126) qualitatively analyzed stomach contents of 12 laurel dace and found the species eats a mixture of food items, dominantly benthic invertebrates, including Trichopteran, Plecopteran, and Dipteran larva. Some intestines contained plant material and sand grains. Skelton observed that the morphological feeding traits of laurel dace, including large mouth, short digestive tract, reduced number of pharyngeal (located within the throat) teeth, and primitively shaped basioccipital bone (bone that articulates the vertebra) are consistent with a diet consisting largely of animal material.

Laurel dace are known historically from seven streams on the Walden Ridge portion of the Cumberland Plateau, where drainages generally meander eastward before dropping abruptly down the plateau escarpment and draining into the Tennessee River. Specifically, these seven streams occur in three independent systems: Soddy Creek; three streams that are part of the Sale Creek system (the Horn and Laurel branch tributaries to Rock Creek, and the Cupp Creek tributary to Roaring Creek); and three streams that are part of the Piney River system (Young's, Moccasin, and Bumbee creeks). Skelton (2001, p. 126) considered collections by the Tennessee Valley Authority (TVA) during a rotenone survey of Laurel Branch in 1976 to represent laurel dace that were misidentified as southern redbelly dace, as was found to be true for specimens collected by TVA from Horn Branch in 1976, but no specimens are available for confirmation. In 1991, and in four other surveys (in 1995, 1996 and 2004), laurel dace were not collected in Laurel Branch, leading Skelton to the conclusion that laurel dace have been extirpated from this stream (Skelton 1997, p. 13; 2001, p. 126, Skelton 2009, pers. comm.). Skelton (2009, pers. comm.) also noted that the site was impacted by silt.

The current distribution of laurel dace comprises six of the seven streams that were historically occupied; the species is considered extirpated from Laurel Branch (see above). In these six streams, they are known to occupy reaches of approximately 0.3 to 8 km (0.2 to 5 mi) in length. The laurel dace is known from a single reach in Soddy Creek, and surveys in 2004 produced only a single, juvenile laurel dace (Strange and Skelton 2005, pp. 5–6 and Appendices 1 and 2). In Horn Branch, laurel dace are known from approximately 900 m (2,953 ft), but have become increasingly difficult to collect (Skelton 1997, pp. 13–14). Skelton (1997, p. 14) reports that minnow traps have been the most successful method for collecting live laurel dace from Horn Branch, as it is difficult to electroshock due to in-stream rock formations and fallen trees. Only a single juvenile was caught in 2004 (Strange and Skelton 2005, p. 6). A total of 19 laurel dace were collected from Cupp Creek during 1995 and 1996 using an electroshocker (Skelton 1996, p. 14). However, Skelton found no laurel dace in this stream in 2004, despite attempts to collect throughout an approximately 700-m (2,297-ft) reach (Strange and Skelton 2005, p. 6).

Laurel dace were initially found in Young's, Moccasin, and Bumbee creeks in the Piney River system in 1996 (Skelton 1997, pp. 14–15). Sampling in 2004 led to the discovery of additional laurel dace localities in Young's and Moccasin creeks, but the locality where laurel dace were found in Young's Creek in 1996 was inaccessible due to the presence of a locked gate (Strange and Skelton 2005, p. 6–7). The new localities were in the headwaters of these two streams. Persistence of laurel dace at the Bumbee Creek locality was confirmed in 2004 by surveying from a nearby road using binoculars. Direct surveys were not possible because the land had been leased to a hunt club for which contact information was not available, and therefore survey permission could not be obtained (Strange and Skelton 2005, p. 7). Nuptial males are easily identified from other species present in Bumbee Creek due to their brilliant coloration during the breeding season, as the two lateral stripes, breast, and underside of head turn intensely black and the entire ventral (lower/abdominal) portion of the body, contiguous with the lower black stripe and black breast, becomes an intense scarlet color. This brilliant coloration is easily seen through binoculars at short distances by trained individuals.

No population estimates are available for laurel dace. However, based on trends observed in surveys and collections since 1991, Strange and Skelton (2005, p. 8) concluded that this species is persisting in Young's, Moccasin, and Bumbee creeks in the Piney River watershed, but is at risk of extirpation from the southern part of Walden Ridge in Soddy Creek, and in the Horn Branch and Cupp Creek areas that are tributaries to Sale Creek. As noted above, the species is considered to be extirpated from Laurel Branch, which is part of the Sale Creek system.

The laurel dace is ranked by the Tennessee Natural Heritage Program (Withers 2009, p. 60) as an S1G1 species: extremely rare in Tennessee, and critically imperiled globally.

In the Tennessee CWCS, species of GCN were selected based on their Global imperilment (G1-G3; critically imperiled globally—very rare or restricted throughout their range), knowledge of declining trends or vulnerability, or due to significance of an otherwise wide-ranging species (TWRA 2005, p. 36). Species of GCN were further prioritized into three different tiers to distinguish their status within the State and to determine conservation funding availability. The CWCS designated the laurel dace as a Tier-1 GCN species in the State, representing species defined as wildlife (amphibians, birds, fish, mammals, reptiles, crustaceans, and mollusks) under Tennessee Code Annotated 70-8-101, and excluding federally listed species (TWRA 2005, p. 44, 49). Tier 1 species were the primary focus of the Tennessee CWCS(TWRA 2005, p. 44).

Previous Federal Action

Cumberland Darter

On September 18, 1985, the Service announced that the Cumberland darter was being considered for possible addition to the List of Endangered and Threatened Wildlife (50 FR 37958). It was assigned a Category 2 status, which was given to those species for which the Service possessed information

indicating that proposing to list as endangered or threatened was possibly appropriate, but for which conclusive data on biological vulnerability and threat was not currently available to support proposed rules. In the 1989, 1991, and 1994 Candidate Notices of Review, the Cumberland darter was again assigned a Category 2 status (54 FR 554, 56 FR 58804, 59 FR 58982).

Assigning categories to candidate species was discontinued in 1996, and only species for which the Service had sufficient information on biological vulnerability and threats to support issuance of a proposed rule were regarded as candidate species (61 FR 7596). Candidate species were also assigned listing priority numbers based on immediacy and the magnitude of threat, as well as their taxonomic status. In the 1999, 2001, 2002, and 2004 Candidate Notices of Review, the Cumberland darter was identified as a listing priority 6 candidate species (64 FR 57533, 66 FR 54807, 67 FR 40657, 69 FR 24875). We published a petition finding for Cumberland darter in the 2005 Candidate Notice of Review (70 FR 24869) in response to a petition received on May 11, 2004. We continued to assign the Cumberland darter a listing priority number of 6, reflecting a threat magnitude and immediacy of high and non-imminent, respectively. In the 2006 Candidate Notice of Review, we changed the listing priority number for Cumberland darter from 6 to 5, because it was formally described as a distinct species (71 FR 53755). Based on new molecular evidence, the subspecies *Etheostoma nigrum susanae* was elevated to specific status, *Etheostoma susanae*. The Cumberland darter continued to be recognized as a listing priority 5 candidate in the 2009 Candidate Notice of Review (74 FR 57869).

Rush Darter

We first identified the rush darter as a candidate for listing in the 2002 Candidate Notice of Review (67 FR 40657). The rush darter was assigned a listing priority number of 5. In the 2004 (69 FR 24875) and 2005 (70 FR 24869) Candidate Notice of Review, the rush darter retained a listing priority number of 5. We published a petition finding for rush darter in the 2005 Candidate Notice of Review (70 FR 24869) in response to a petition received on May 11, 2004. The rush darter retained a listing priority number of 5 in the 2005 Candidate Notice of Review (70 FR 24869), in accordance with our priority guidance published on September 21, 1983 (48 FR 43098).

In 2006, we changed the listing priority number of the rush darter from 5 to 2 based on the imminent threat of water quality deterioration (i.e., increased sedimentation due to urbanization, road maintenance, and silviculture practices) (71 FR 53755). In the 2009 Candidate Notice of Review (74 FR 57869), the rush darter retained a listing priority of 2.

Yellowcheek Darter

We first identified the yellowcheek darter as a candidate for listing in the 2001 Candidate Notice of Review (66 FR 54807). The yellowcheek darter was assigned a listing priority number of 2 and has retained that status in the 2002, 2004, 2005, 2006, 2007, 2008, and 2009 Candidate Notices of Review (67 FR 40657, 69 FR 24875, 70 FR 24869, 71 FR 53755, 72 FR 69073, 73 FR 75175). We published a petition finding for yellowcheek darter in the 2005 Candidate Notice of Review in response to a petition received on May 11, 2004 (70 FR 24869). The yellowcheek darter is covered by a 2007 programmatic Candidate Conservation Agreement with Assurances (71 FR 53129) that covers the entire range of the species.

Chucky Madtom

We first identified the chucky madtom as a possible candidate for listing in the 1994 Candidate Notice of Review (59 FR 58982). It was assigned a Category 2 status, which was given to those species for which the Service possessed information indicating that proposing to list as endangered or threatened was possibly appropriate, but for which persuasive data on biological vulnerability and threat was not currently available to support proposed rules. In the 2002, 2004, 2005, 2006, 2007, 2008, and 2009 Candidate Notices of Review, the chucky madtom was again identified as a listing priority 2 candidate species (67 FR 40657, 69 FR 24875, 70 FR 24869, 71 FR 53755, 72 FR 69033, 73 FR 75236, 74 FR 57869).

We published a petition finding for chucky madtom in the 2005 Candidate Notice of Review (70 FR 24869) in response to a petition received on May 11, 2004, stating the chucky madtom would retain a listing priority of 2.

In 1994, the chucky madtom was first added to the candidate list as *Noturus* sp. (59 FR 58982). Subsequently, and based on morphological and molecular evidence, the chucky madtom was formally described as a distinct species, *Noturus crypticus* (Burr *et al.* 2005). We included this new information in the 2006 Candidate Notice of Review (71 FR 53755).

Laurel Dace

We first identified the laurel dace as a new candidate for listing in the 2007 Candidate Notice of Review (72 FR 69036). New candidates are those taxa for which we have sufficient information on biological vulnerability and threats to support preparation of a listing proposal, but for which development of a listing regulation is precluded by other higher priority listing activities.

In the 2007 Candidate Notice of Review, we assigned the laurel dace a listing priority of 5 (72 FR 69036), and it was again identified as a listing priority 5 candidate species in the 2008 and 2009 Candidate Notices of Review (73 FR 75236, 74 FR 57869). This number reflects the high magnitude and non-imminence of threats to the species.

Summary of Factors Affecting the Species

Section 4 of the Act (16 U.S.C 1533), and its implementing regulations (50 CFR Part 424), set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. We may determine a species to be endangered or threatened due to one or more of the five factors described in section 4(a)(1) of the Act. The five listing factors are: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; and (E) other natural or manmade factors affecting its continued existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination. Each of these factors is discussed below.

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

The primary threat to the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace is physical habitat destruction/modification resulting from a variety of human-induced impacts such as siltation, disturbance of riparian corridors, and changes in channel morphology (Waters 1995, pp. 2–3; Skelton 1997, pp. 17, 19; Thomas 2007, p. 5). The most significant of these impacts is siltation (excess sediments suspended or deposited in a stream) caused by excessive releases of sediment from activities such as resource extraction (e.g., coal mining, silviculture, natural gas development), agriculture, road construction, and

urban development (Waters 1995, pp. 2–3; KDOW 2006, pp. 178–185; Skelton 1997, pp. 17, 19; Thomas 2007, p. 5).

Land use practices that affect sediment and water discharges into a stream can also increase the erosion or sedimentation pattern of the stream, which can lead to the destruction or modification of in-stream habitat and riparian vegetation, stream bank collapse, and increased water turbidity and temperature. Sediment has been shown to abrade and or suffocate bottom-dwelling algae and other organisms by clogging gills; reducing aquatic insect diversity and abundance; impairing fish feeding behavior by altering prey base and reducing visibility of prey; impairing reproduction due to burial of nests; and, ultimately, negatively impacting fish growth, survival, and reproduction (Waters 1995, pp. 5–7, 55–62; Knight and Welch 2001, pp. 134–136). Wood and Armitage (1997, pp. 211–212) identified at least five impacts of sedimentation on fish, including (1) reduction of growth rate, disease tolerance, and gill function; (2) reduction of spawning habitat and egg, larvae, and juvenile development; (3) modification of migration patterns; (4) reduction of food availability through the blockage of primary production; and (5) reduction of foraging efficiency. The effects of these types of threats will likely increase as development increases in these watersheds.

Non-point source pollution from land surface runoff can originate from virtually any land use activity and may be correlated with impervious surfaces and storm water runoff. Pollutants may include sediments, fertilizers, herbicides, pesticides, animal wastes, septic tank and gray water leakage, pharmaceuticals, and petroleum products. These pollutants tend to increase concentrations of nutrients and toxins in the water and alter the chemistry of affected streams such that the habitat and food sources for species like the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace are negatively impacted. Construction and road maintenance activities associated with urban development typically involve earth-moving activities that increase sediment loads into nearby streams. Other siltation sources, including timber harvesting, natural gas development activities, clearing of riparian vegetation, mining, and agricultural practices, allow exposed earth to enter streams during or after precipitation events. These activities result in canopy removal, elevated stream temperatures, and increased siltation, thereby degrading habitats used by fishes for both feeding and reproduction (Mattingly *et al.* 2005, p. 5). Undisturbed riparian corridors are important because they prevent elevated stream temperatures due to solar heating, serve as buffers against non-point source pollutants, provide submerged root materials for cover and feeding, and help to stabilize stream banks (Mattingly *et al.* 2005, p. 5).

Cumberland Darter

The Cumberland darter's preferred habitat characteristics (i.e., low- to moderate-gradient, low current velocity, backwater nature) make it extremely susceptible to the effects of siltation (O'Bara 1991, p. 11). Sediment (siltation) has been listed repeatedly by the Kentucky Natural Resources and Environmental Protection Cabinet (Division of Water) as the most common stressor of aquatic communities in the upper Cumberland River basin (KDOW 1996, pp. 50–53, 71–75; 2002, pp. 39–40; 2006, pp. 178–185). The primary source of sediment was identified as resource extraction (e.g., coal mining, logging). The streams within the Cumberland darter's current range that are identified as impaired (due to siltation from mining, logging, and agricultural activities) and have been included on Kentucky's 303(d) list of impaired waters (KDOW 2007, pp. 155–166) include Jenneys Branch (Indian Creek basin), an unnamed tributary of Jenneys Branch (Indian Creek basin), Ryans Creek (Jellico Creek basin), Marsh Creek, and Wolf Creek (Clear Fork basin).

Siltation can also occur in the Cumberland darter's known habitat as a result of construction activities for human development. For example, during the fall of 2007, an 8.4-km (5.2-mi) reach of Barren Fork in McCreary County, Kentucky, was subjected to a severe sedimentation event (Floyd 2008, pers. obs.). This event occurred despite the fact that approximately 95 percent of the Barren Fork watershed is under Federal ownership within the Daniel Boone National Forest (DBNF). Construction activities associated with the development of a 40.47-hectare (100-acre) park site caused excessive sedimentation of two unnamed headwater tributaries of Barren Fork. Successive, large rainfall events in September and October carried sediment off site and impacted downstream areas of Barren Fork known to support Cumberland darters and the Federally threatened blackside dace. Our initial site visit on September 7, 2007, confirmed that sediment had been carried off site, resulting in significant habitat degradation in the Barren Fork mainstem and "adverse effects" on the blackside dace. Several smaller sediment events have occurred despite Federal and State attempts to resolve the issue, and on July 31, 2008, another large rainfall event resulted in excessive sedimentation in two Barren Fork watershed streams.

Another significant threat to the Cumberland darter is water quality degradation caused by a variety of non-point source pollutants. Coal mining represents a major source of these pollutants (O'Bara 1991, p. 11; Thomas 2007, p. 5), because it has the potential to contribute high concentrations of dissolved metals and other solids that lower stream pH or lead to elevated levels of stream conductivity (Pond 2004, pp. 6–7, 38–41; Mattingly *et al.* 2005, p. 59). These impacts have been shown to negatively affect fish species, including listed species, in the Clear Fork system of the Cumberland basin (Weaver 1997, pp. 29; Hartowicz 2008, pers. comm.). The direct effect of elevated stream conductivity on fishes, including the Cumberland darter, is poorly understood, but some species, such as blackside dace, have shown declines in abundance over time as conductivity increased in streams affected by mining (Hartowicz 2008, pers. comm.). Studies indicate that blackside dace are generally absent when conductivity values exceed 240 microSiemens (μS) (Mattingly *et al.* 2005, p. 59; Black and Mattingly 2007, p. 12).

Other non-point source pollutants that affect the Cumberland darter include domestic sewage (through septic tank leakage or straight pipe discharges); agricultural pollutants such as fertilizers, pesticides, herbicides, and animal waste; and other chemicals associated with oil and gas development. Non-point source pollutants can cause excess nutrification (increased levels of nitrogen and phosphorus), excessive algal growth, instream oxygen deficiencies, increased acidity and conductivity, and other changes in water chemistry that can seriously impact aquatic species (KDOW 1996, pp. 48–50; KDOW 2006, pp. 70–73).

In summary, habitat loss and modification represent significant threats to the Cumberland darter. Severe degradation from sedimentation, physical habitat disturbance, and contaminants threatens the habitat and water quality on which the Cumberland darter depends. Sedimentation from coal mining, silviculture, agriculture, and development sites within the upper Cumberland basin negatively affect the

Cumberland darter by reducing growth rates, disease tolerance, and gill function; reducing spawning habitat, reproductive success, and egg, larvae, and juvenile development; modifying migration patterns; reducing food availability through reductions in prey; and reducing foraging efficiency. Contaminants associated with coal mining (metals, other dissolved solids), domestic sewage (bacteria, nutrients), and agriculture (fertilizers, pesticides, herbicides, and animal waste) cause degradation of water quality and habitats through increased acidity and conductivity, instream oxygen deficiencies, excess nutrification, and excessive algal growths. Furthermore, these threats faced by the Cumberland darter from sources of sedimentation and contaminants are imminent; the result of ongoing projects that are expected to continue indefinitely. As a result of the imminence of these threats combined with the vulnerability of the remaining small populations to extirpation from natural and manmade threats, we have determined that the present or threatened destruction, modification, or curtailment of the Cumberland darter habitat and range represents a significant threat of high magnitude. We have no information indicating that the magnitude or imminence of this threat is likely to be appreciably reduced in the foreseeable future.

Rush Darter

Sediment is the most abundant pollutant in the Mobile River Basin (Alabama Department of Environmental Management 1996, pp. 14–15). Within the Clear Creek drainage, Johnston and Kleiner (2001, p. 4) reported that during August 2001, land uses in the Doe Branch and Mill Creek area appeared to be dominated by forests, and that there were no obvious threats to water quality. However, Johnston and Kleiner (2001, p. 4) reported that clear cutting in the Wildcat Branch watershed may have increased sedimentation into the stream. Approximately 84 percent (i.e., 5 km or 3 mi) of Wildcat Branch is privately owned, and recent land exchanges within the Bankhead National Forest have taken about 0.9 km (0.6 mi) of stream west of Clear Creek out of U.S. Forest Service (USFS) management and protection. In 2001, Service and USFS personnel noted heavy siltation at the County Road 329 Bridge over Doe Branch during a modest spring rain and also noted heavy siltation at several other road crossings and in other tributary streams in the immediate area. Drennen (2005, pers. obs.) noted increasing erosion and deepening of roadside ditches, and erosion of the gravel County Road 329 at Doe and Wildcat branches, contributing to the sediment in these streams.

Blanco (2001, p. 68) identified siltation from development projects as the greatest threat to the fauna of Turkey Creek. Point source siltation sites have impacted the Turkey Creek watershed, including four sites affecting Beaver Creek, a major tributary to Turkey Creek. These sites included bridge, road, and sewer line construction sites and a wood pallet plant (Drennen 1999, pers. obs.). In addition, Turkey Creek at the confluence of Tapawingo and Penny Springs is often sediment laden and completely turbid after medium to heavy rainfall. Rapid urbanization in this area renders this population extremely vulnerable during the breeding season when rush darters concentrate in wetland pools and shallow pools with aquatic vegetation in headwater streams (Stiles and Mills 2008, p. 5; Fluker *et al.* 2007, p. 10).

Four major soil types occur within the Turkey Creek watershed, and all are considered highly erodible due to the steep topography (Spivey 1982, pp. 5, 7, 8, 14). Therefore, any activity that removes native vegetation on these soils can be expected to lead to increased sediment loads in Turkey Creek (USFWS 2001, p. 59370), including the areas near Penny and Tapawingo Springs. Industrialization is extensive and expanding throughout the watershed, particularly near the type locality for the rush darter (Bart and Taylor 1999, p. 33; Drennen 2007, pers. obs.).

Abundant water from springs throughout the rush darter's range, especially in Pinson Valley, Alabama, is needed as a flushing effect to provide constant cleansing of the streams with cool, fresh water. However, ongoing destruction of spring heads and wetlands has significantly reduced the species' movement and colonization. Little Cove Creek and Bristow Creek spring heads have been channelized, and the head of Cove Spring has a pumping facility built on it (Fluker *et al.* 2007, p. 1). Spring water in these systems may be more impacted by site-specific spring head disturbances rather than overall spring drainage disturbances (Drennen 2005, per. obs.). Alteration of spring head habitats has reduced water quality and increased sediment loads into spring-fed tributary streams throughout the range of the rush darter.

In summary, the most significant threat to rush darters is siltation, caused by an increase in urbanization surrounding the streams and springs, road maintenance and silviculture practices. This threat is ongoing and thus considered imminent. The magnitude of the threat is high due to the small population and high levels of siltation in the springs and streams. We have no information indicating that the magnitude or imminence of this threat is likely to be appreciably reduced in the foreseeable future.

Yellowcheek Darter

Robison and Harp (1981, p. 17), McDaniel (1984, p. 92), and Robison and Buchanan (1988, p. 429) have attributed the decline in populations of yellowcheek darters in the four forks of the Little Red River and main stem Little Red River to habitat alteration and degradation. The suspected primary cause of the species' decline is the impoundment of the Little Red River and lower reaches of the Devils, Middle, and South Forks, areas that in the past provided optimal habitat for this species. The creation of Greers Ferry Lake in 1962 converted optimal yellowcheek darter habitat (clear, cool, perennial flow with large substrate particle size (Robison and Buchanan 1988, p. 429)), to a deep, standing water environment. This dramatic change in habitat flooded spawning sites, altered habitat radically, and changed chemical and physical characteristics in the streams which provide optimal habitat for this species. Impoundments profoundly alter channel characteristics, habitat availability, and flow regime with serious consequences for biota (Allan and Flecker 1993, p. 36, Ward and Stanford 1995, pp. 105–119). Some of these include converting flowing to still waters, increasing depths and sedimentation, decreasing dissolved oxygen, drastically altering resident fish populations (Neves *et al.* 1997, p. 63), disrupting fish migration, and destroying spawning habitat (Ligon *et al.* 1995, pp. 185–86). Channelization of the lower 5.6 km (3.5 miles) of Archey and South Forks in 1985 and subsequent channel maintenance to this day by the U.S. Army Corps of Engineers and City of Clinton, Arkansas, degraded habitat in this reach as well as segments upstream of the project area. Based upon current knowledge and a 2004-2005 threats assessment (Davidson and Wine 2004, pp. 6–13; Davidson 2005, pp. 1–4), gravel mining, unrestricted cattle access into streams, water withdrawal for agricultural and recreational purposes (i.e., golf courses), lack of adequate riparian buffers, construction and maintenance of county roads, and non-point source pollution arising from a broad array of activities

also appear to be degrading suitable habitat for the species. The threats assessment documented occurrences of the aforementioned activities and found 52 sites on the Middle Fork, 28 sites on the South Fork, 8 sites on Archey Fork (Davidson 2005, pp. 1–4), and 1 site in the Turkey/Beech/Devils Fork system that are adversely affected by these activities and likely contributors to the decline of the species.

Yellowcheek darter numbers have declined by 83 percent in both the Middle Fork and South Fork of the Upper Little Red River watershed, and 60 percent in the Archey Fork in the past 20 years. Yellowcheek darter was not found in the Turkey Fork reach of the Devils Fork during the 2000 status survey, and is presumed to be extirpated in this reach. A comparison of inhabited stream reaches in the 1981 survey versus the 2000 survey reveals that the largest decline occurred in the South Fork, where reaches formerly inhabited by the yellowcheek darter declined by 70 percent. The second largest decline occurred in the Archey Fork, where there was a 60 percent reduction in inhabited stream reach. The Middle Fork showed the least decline in inhabited stream reach, at 22 percent.

Ozark headwater streams typically exhibit seasonal fluctuations in flows, with flow rates highest in spring, and lowest in late summer and fall. The upper reaches of these small streams are most affected by seasonally fluctuating water levels (Robison and Harp 1981, p. 17). As a result, they often lack consistent and adequate flows, and by late summer or fall are reduced to a series of isolated pools (Wine 2008, pers. comm.). Expanding natural gas development activities that began in the upper Little Red River watershed in 2006 require large quantities of water and pose an imminent threat to the continued existence of yellowcheek darter as these activities rapidly expand and increase in the watersheds of all four forks (Davidson 2008, pers. comm.). Because the yellowcheek darter requires permanent flows with moderate to strong current (Robison and Buchanan 1988, p. 429), and because downstream refugia have been lost, seasonal fluctuations in stream flows that reduce moving water (lotic habitat) to a series of isolated pool habitats are a serious threat.

Additional contributors to yellowcheek declines and continuing threats include habitat degradation from land use activities in the watershed, including agriculture and forestry. Traditional farming practices, feed-lot operations, and associated poor land use practices contribute many pollutants to rivers. Neves *et al.* (1997, p. 65) suggest that agriculture affects 72 percent of impaired river reaches in the United States. Nutrients, bacteria, pesticides, and other organic compounds generally are found in higher concentrations in agricultural areas than forested areas. Nutrient concentrations in streams may result in increased algal growth in streams, and a related alteration in fish community composition (Petersen *et al.* 1999, p. 16). Major agricultural activities within the Little Red River watershed include poultry, dairy, swine, and beef cattle operations.

The Arkansas Natural Resources Conservation Service has identified animal wastes, nutrients, excessive erosion, loss of plant diversity, and declining species as water quality concerns associated with agricultural land use activities in the upper Little Red River watershed (NRCS 1999). Large poultry and dairy operations increase nutrient inputs to streams when producers apply animal waste to pastures to stimulate vegetation growth for grazing and hay production. Continuous grazing methods in the watershed allow unrestricted animal access to grazing areas, and on steeper slopes this results in increased runoff and erosion (NRCS 1999). Since pastures often extend directly to the edge of the stream, and lack a riparian zone with native vegetation, runoff from pastures carries pollutants directly into streams. Eroding stream banks also result in alterations to stream hydrology and geomorphology, degrading habitat. Livestock spend a disproportionate amount of time in riparian areas during hot summer months. Trampling and grazing can change and reduce vegetation and eliminate riparian areas by channel widening, channel aggradation, or lowering of the water table (Armour *et al.* 1991, pp. 7–11).

Additionally, earthen dams were constructed across a riffle in the lower South Fork to create a pool for annual chuck wagon races for many years leading up to 2003. The Service and U.S. Army Corps of Engineers met with the responsible landowner in 2004 and suggested an alternative to dam construction that would minimize impacts to the yellowcheek darter. These recommendations were followed for several years; however, another earthen dam was constructed in 2008 using material from the South Fork to facilitate events associated with the annual chuck wagon races. This dam, like its predecessors, was unpermitted and resulted in significant habitat degradation and alteration for several miles upstream and downstream of the site.

The chuck wagon race event draws approximately 20,000 to 30,000 people per year to the South Fork Little Red River for a 1–week period around Labor Day. Horses and wagons traverse the river and its tributaries for miles leading to increased habitat disturbance, sedimentation, and trampling. The chuck wagon races continue to grow annually and pose a significant threat to the continued existence of yellowcheek darters in the South Fork Little Red River.

Timber harvesting activities involving clear-cutting entire steep hillsides were observed during 1999-2000 in the Devils Fork watershed (Wine 2008, pers. comm.). The failure to implement voluntary State best management practices (BMPs) for intermittent and perennial streams during timber harvests has resulted in water quality degradation and habitat alteration in stream reaches adjacent to harvesting operations. When timber harvests involve clear cutting to the water's edge, without leaving a riparian buffer, silt and sediment enter streams lying at the bottom of steep slopes. The lack of stream side vegetation also promotes bank erosion that alters stream courses and introduces large quantities of sediment into the channel (Allan 1995, p. 321). Timber harvest operations that use roads on steep slopes to transport timber can carry silt and sediment from the road into the stream at the bottom of the slope. Logging impacts on sediment production are considerable, but often erosion of access and haul roads produces more sediment than the land harvested for timber (Brim Box and Mossa 1999, p. 102). These activities have occurred historically and continue to occur in the upper Little Red River watershed.

Natural gas exploration and development is a newly emerging threat to yellowcheek darter populations. Significant erosion and sedimentation issues associated with natural gas development activities, particularly pipelines (herein defined as all flow lines, gathering lines, and non-interstate pipelines), were first documented by Service biologists during 2007 in the South Fork Little Red River watershed. In June 2008, the Service began documenting significant erosion and sedimentation issues associated with natural gas pipeline construction and maintenance as natural gas development activities expanded into the watershed. Service biologists documented significant erosion and sedimentation at almost every new pipeline stream crossing in the South Fork and Middle Fork Little Red River watersheds, regardless of the diameter of the pipe.

Channel incision was documented at numerous stream crossings that are tributaries to the South Fork Little Red River. The incision increased erosion and sedimentation, as well as altering the hydrology and geomorphology characteristics of the streams. Pipeline rights-of-way were found to have one of the following conditions: (1) no BMPs (i.e., silt fences, grade breaks, non-erodible stream crossing materials) installed to prevent erosion and sedimentation, (2) ineffective erosion minimization practices in place, (3) effective erosion minimization practices that had not been maintained and, thus, had become ineffective, or (4) final reclamation of the pipeline right-of-way had not occured for months and in some cases greater than a year after construction activities ceased leading to prolonged periods of erosion and sedimentation. The magnitude of the impacts to the South Fork and Middle Fork Little Red River from 2007-2008 also was exacerbated due to above average rainfall, which led to more frequent and larger pipeline erosion events.

In summary, threats to the yellowcheek darter from the present destruction, modification, or curtailment of its habitat or range negatively impact the species. Threats include such activities as impoundment, sedimentation (from a broad array of activities), nutrient enrichment, gravel mining, channelization/channel instability, and natural gas development. These threats are considered imminent and of high magnitude throughout the species' entire range. We have no information indicating that the magnitude or imminence of these threats is likely to be appreciably reduced in the foreseeable future, and in the case of pipeline disturbance, we expect this threat to become more problematic over the next several years as natural gas development continues to intensify.

Chucky Madtom

The current range of the chucky madtom is believed to be restricted to an approximately 1.8-mi (3-km) reach of Little Chucky Creek in Greene County, Tennessee. Land use data from the Southeast GAP Analysis Program (SE-GAP) show that land use within the Little Chucky Creek watershed is predominantly dominated by agricultural use, with the vast majority of agricultural land being devoted to production of livestock and their forage base (USGS 2008).

Traditional farming practices, feed-lot operations, and associated land use practices contribute many pollutants to rivers. Neves *et al.* (1997, p. 65) suggest that agriculture affects 72 percent of impaired river reaches in the United States. These practices erode stream banks and result in alterations to stream hydrology and geomorphology, degrading habitat. Nutrients, bacteria, pesticides, and other organic compounds generally are found in higher concentrations in agricultural areas than forested areas. Nutrient concentrations in streams may result in increased algal growth in streams, and a related alteration in fish community composition (Petersen *et al.* 1999, p. 16).

The TVA Index of Biological Integrity results indicate that Little Chucky Creek is biologically impaired (Middle Nolichucky Watershed Alliance 2006, p. 13). Given the predominantly agricultural land use within the Little Chucky Creek watershed, non-point source sediment and agrochemical discharges may pose a threat to the chucky madtom by altering the physical characteristics of its habitat, thus potentially impeding its ability to feed, seek shelter from predators, and successfully reproduce. The Little Chucky Creek watershed also contains a portion of the city of Greeneville, providing an additional source for input of sediments and contaminants into the creek and threatening the chucky madtom. Wood and Armitage (1997, pp. 211–212) identify at least five impacts of sedimentation on fish, including (1) reduction of growth rate, disease tolerance, and gill function; (2) reduction of spawning habitat and egg, larvae, and juvenile development; (3) modification of migration patterns; (4) reduction of food availability through the blockage of primary production; and (5) reduction of foraging efficiency.

The chucky madtom is a bottom-dwelling species. Bottom-dwelling fish species are especially susceptible to sedimentation and other pollutants that degrade or eliminate habitat and food sources (Berkman and Rabeni 1987, pp. 290–292; Richter *et al.* 1997, p. 1091; Waters 1995, p. 72). Etnier and Jenkins (1980, p. 20) suggested that madtoms, which are heavily dependent on chemoreception (detection of chemicals) for survival, are susceptible to human-induced disturbances, such as chemical and sediment inputs, because the olfactory (sense of smell) "noise" they produce could interfere with a madtom's ability to obtain food and otherwise monitor its environment.

In summary, threats to the chucky madtom from the present destruction, modification, or curtailment of its habitat or range negatively impact the species. Degradation from sedimentation, physical habitat disturbance, and contaminants threaten the habitat and water quality on which the chucky madtom depends. Sedimentation from agricultural lands could negatively affect the chucky madtom by reducing growth rates, disease tolerance, and gill function; reducing spawning habitat, reproductive success, and egg, larvae, and juvenile development; reducing food availability through reductions in prey; and reducing foraging efficiency. Contaminants associated with agriculture (e.g., fertilizers, pesticides, herbicides, and animal waste) can cause degradation of water quality and habitats through instream oxygen deficiencies, excess nutrification, and excessive algal growths. Furthermore, these threats faced by the chucky madtom from sources of sedimentation and contaminants are imminent; the result of ongoing agricultural practices that are expected to continue indefinitely. As a result of the imminence of these threats combined with the vulnerability of the remaining small population to extirpation from natural and manmade threats, we have determined that the present or threatened destruction, modification, or curtailment of the chucky madtom habitat and range represents a significant threat of high magnitude. We have no information indicating that the magnitude or imminence of these threats is likely to be appreciably reduced in the foreseeable future.

Laurel Dace

Skelton (2001, p. 127) concluded that the laurel dace is "presumably tolerant of some siltation." However, Strange and Skelton (2005, p. 7 and Appendix 2) observed levels of siltation they considered problematic during later surveys for the laurel dace and concluded this posed a threat in several localities throughout the range of the species. Sediment has been shown to abrade and or suffocate bottom-dwelling fish and other organisms by clogging gills; reducing aquatic insect diversity and abundance; impairing fish feeding behavior by altering prey base and reducing visibility of prey; impairing reproduction due to burial of nests; and, ultimately, negatively impacting fish growth, survival, and reproduction (Waters 1995, pp. 5–7, 55–62; Knight and Welch 2001, pp. 134–136). However, we do not currently know what levels of siltation laurel dace are able to withstand before populations begin to decline due to these siltation-related stressors. The apparent stability of the northern population of laurel dace in the Piney River system suggests

that this species is at least moderately tolerant of siltation-related stressors. We do not know the extent to which other factors might have driven the decline of the southern populations in Sale and Soddy Creeks.

Of the streams inhabited by the southern populations recognized by Strange and Skelton (2005, p. Appendix 2), the reaches from which laurel dace have been collected in Soddy Creek and Horn Branch approach 0.6 mi (1 km) in length. In Cupp Creek, collections of this species are restricted to less than 984 ft (300 m) of stream, in spite of surveys well beyond the reach known to be inhabited. In each of the streams occupied by the southern populations, Strange and Skelton (2005, Appendix 2) identified siltation as a factor that could alter the habitat and render it unsuitable for laurel dace. The restricted distribution of laurel dace in streams inhabited by the southern populations leaves them highly vulnerable to potential deleterious effects of excessive siltation or other localized disturbances.

A newly emerging threat to laurel dace in Soddy Creek is the conversion of pine plantations to row crop agriculture. Two large plantations within the Soddy Creek Watershed were harvested and then converted to tomato farms. An irrigation impoundment was built on one Soddy Creek tributary and another is under construction. As a result of these activities, a large silt source was introduced into the Soddy Creek headwaters. In addition to contributing sediment, crop fields often allow runoff from irrigation water to flow directly into the creek. This water contains fungicides, herbicides, and fertilizers (Thurman 2010, pers. comm.).

Strange and Skelton (2005, p. 7 and Appendix 2) identified siltation as a threat in all of the occupied Piney River tributaries (Young's, Moccasin, and Bumbee Creeks). The Bumbee Creek type locality for the laurel dace is located within industrial forest that has been subjected to extensive clear-cutting and road construction in close proximity to the stream. Strange and Skelton (2005, p. 7) noted a heavy sediment load at this locality and commented that conditions there in 2005 had deteriorated since the site was visited by Skelton in 2002. Strange and Skelton (2005, pp. 7 and 8 and Appendix 2) also commented on excessive siltation in localities they sampled on Young's and Moccasin Creeks, and observed localized removal of riparian vegetation around residences in the headwaters of each of these streams. They considered the removal of riparian vegetation problematic not only for the potential for increased siltation, but also for the potential thermal alteration of these small headwater streams. Skelton (2001, p. 125) reported that laurel dace occupy cool streams with a maximum recorded temperature of 26° C (78.8° F). The removal of riparian vegetation could potentially increase temperatures above the laurel dace's maximum tolerable limit.

Water temperature may be a limiting factor in the distribution of this species (Skelton 1997, pp. 17, 19). Canopy cover of laurel dace streams often consists of eastern hemlock, mixed hardwoods, pine, and mountain laurel. The hemlock woolly adelgid (*Adelges tsugae*) is a nonnative insect that infests hemlocks, causing damage or death to trees. The woolly adelgid was recently found in Hamilton County, Tennessee, and could impact eastern hemlock in floodplains and riparian buffers (land adjacent to stream channels) along laurel dace streams in the future (Simmons 2008, pers. comm.). Riparian buffers filter sediment and nutrients from overland runoff, allow water to soak into the ground, protect stream banks and lakeshores, and provide shade for streams. Because eastern hemlock is primarily found in riparian areas, the loss of this species adjacent to laurel dace streams would be detrimental to fish habitat.

Habitat destruction and modification also stem from existing or proposed infrastructure development in association with timber harvesting. The presence of culverts at one or more road crossings in most of the streams inhabited by laurel dace may disrupt upstream dispersal within those systems (Chance 2008, pers. obs.). Such dispersal barriers could prevent re-establishment of laurel dace populations in reaches where they suffer localized extinctions due to natural or human-caused events.

In summary, the primary threat to laurel dace throughout its range is excessive siltation resulting from agriculture and extensive timber harvesting involving both inadequate riparian buffers in harvest areas and the failure to use best management practices in road construction. Severe degradation from sedimentation, physical habitat disturbance, and contaminants threatens the habitat and water quality on which the laurel dace depends. Sedimentation from negatively affects the laurel dace by reducing growth rates, disease tolerance, and gill function; reducing spawning habitat, reproductive success, and egg, larvae, and juvenile development; reducing food availability through reductions in prey; and reducing foraging efficiency. These threats faced by the laurel dace from sources of sedimentation and contaminants are imminent; the result of ongoing agriculture and forestry practices that are expected to continue. As a result of the imminence of these threats, we have determined that the present or threatened destruction, modification, or curtailment of the laurel dace habitat and range represents a significant threat of high magnitude. We have no information indicating that the magnitude or imminence of these threats is likely to be appreciably reduced in the foreseeable future.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

The Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace are not commercially utilized. Individuals have been taken for scientific and private collections in the past, but collecting is not considered a factor in the decline of these species and is not expected to be so in the future. The available information does not indicate that overutilization is likely to become a threat to any of these five fishes in the foreseeable future.

C. Disease or Predation

Disease is not considered to be a factor in the decline of the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, or laurel dace. Although the Cumberland darter, rush darter, yellowcheek darter, and laurel dace are undoubtedly consumed by predators, the available information suggests that this predation is naturally occurring, or a normal aspect of the population dynamics. As a result, we do not believe that predation is considered to currently pose a threat to these species. Furthermore, the information we do have, does not indicate that disease or predation is likely to become a threat to any of these five fishes in the foreseeable future.

D. The Inadequacy of Existing Regulatory Mechanisms

Cumberland Darter

The Cumberland darter and its habitats are afforded some protection from water quality and habitat degradation under the Clean Water Act of 1977 (33 U.S.C. 1251 *et seq.*), Kentucky's Forest Conservation Act of 1998 (KRS 149.330-355), Kentucky's Agriculture Water Quality Act of 1994 (KRS 224.71-140), additional Kentucky laws and regulations regarding natural resources and environmental protection (KRS 146.200-360; KRS 224; 401 KAR 5:026, 5:031), and Tennessee's Water Quality Control Act of 1977 (T.C.A. 69-

3-101). However, as demonstrated under Factor A, population declines and degradation of habitat for this species are ongoing despite the protection afforded by these laws and corresponding regulations. While these laws have resulted in some improvements in water quality and stream habitat for aquatic life, including the Cumberland darter, they alone have not been adequate to fully protect this species; sedimentation and non-point source pollutants continue to be a significant problem.

States maintain water-use classifications through issuance of National Pollutant Discharge Elimination System (NPDES) permits to industries, municipalities, and others that set maximum limits on certain pollutants or pollutant parameters. For water bodies on the 303(d) list, States are required under the Clean Water Act to establish a total maximum daily load (TMDL) for the pollutants of concern that will bring water quality into the applicable standard. Three Cumberland darter streams, Jenneys Branch, Marsh Creek, and Wolf Creek, have been identified as impaired by the Kentucky Division of Water and placed on the State's 303(d) list (KDOW 2008). Causes of impairment were listed as siltation/sedimentation from agriculture, coal mining, land development, and silviculture and organic enrichment/eutrophication from residential areas. TMDLs have not yet been developed for these pollutants.

The Cumberland darter has been designated as an endangered species by Tennessee (TWRA 2005, p. 240) and Kentucky (KSNPC 2005, p. 11), but the designation in Kentucky conveys no legal protection. Under the Tennessee Nongame and Endangered or Threatened Wildlife Species Conservation Act of 1974 (Tennessee Code Annotated §§ 70-8-101-112), "[I]t is unlawful for any person to take, attempt to take, possess, transport, export, process, sell or offer for sale or ship nongame wildlife, or for any common or contract carrier knowingly to transport or receive for shipment nongame wildlife." Further, regulations included in the Tennessee Wildlife Resources Commission Proclamation 00-15 Endangered Or Threatened Species state the following: "Except as provided for in Tennessee Code Annotated, Section 70-8-106 (d) and (e), it shall be unlawful for any person to take, harass, or destroy wildlife listed as threatened or endangered or otherwise to violate terms of Section 70-8-105 (c) or to destroy knowingly the habitat of such species without due consideration of alternatives for the welfare of the species listed in (1) of this proclamation, or (2) the United States list of Endangered fauna." Under these regulations, potential collectors of this species are required to have a State collection permit. However, in terms of project management, this regulation only provides for the consideration of alternatives, and does not require the level of project review afforded by the Act.

In 7 of 12 streams where the Cumberland darter still occurs, the species is indirectly provided some protection from Federal actions and activities through the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), because these streams (or basins) also support the Federally threatened blackside dace and occupy watersheds that are at least partially owned by the Federal government (Daniel Boone National Forest). The five remaining streams supporting populations of the Cumberland darter are not afforded this protection.

In summary, population declines and degradation of habitat for the Cumberland darter are ongoing despite the protection afforded by State and Federal laws and corresponding regulations. Because of the vulnerability of the small remaining populations of the Cumberland darter and the imminence of these threats, we find the inadequacy of existing regulatory mechanisms to be a significant threat of high magnitude. Further, the information available to us at this time does not indicate that the magnitude or imminence of this threat is likely to be appreciably reduced in the foreseeable future.

Rush Darter

The rush darter and its habitats are afforded some protection from water quality and habitat degradation under the Clean Water Act and the Alabama Water Pollution Control Act, as amended, 1975 (Code of Alabama, §§ 22-22-1 to 22-22-14). However, as demonstrated under Factor A, population declines and degradation of habitat for this species are ongoing despite the protection afforded by these laws. While these laws have resulted in some improvement in water quality and stream habitat for aquatic life, including the rush darter, they alone have not been adequate to fully protect this species; sedimentation and non-point source pollutants continue to be a significant problem. Sediment is the most abundant pollutant in the Mobile River Basin and the greatest threat to the rush darter. There are currently no requirements within the scope of other environmental laws within Alabama to specifically consider the rush darter or ensure that a project will not jeopardize its continued existence.

The State of Alabama maintains water-use classifications through issuance of NPDES permits to industries, municipalities, and others that set maximum limits on certain pollutants or pollutant parameters. For water bodies on the 303(d) list, States are required under the Clean Water Act to establish a TMDL for the pollutants of concern that will bring water quality into the applicable standard. The State of Alabama has not identified any impaired water bodies in Jefferson, Winston, and Etowah Counties in the immediate or upstream portion of the rush darter range or watersheds in Winston or Etowah County. However, sedimentation events are usually related to the stormwater runoff episodes, and are usually not captured by routine water quality sampling. Although stormwater events are temporary, they are still very significant and destructive to the species, habitat, vegetation and food sources, as previously mentioned. When the stormwater water events abate, the water becomes more hospitable to the species, due to the spring influences and constant flushing from spring water. Thus, there is no listing or label for these bodies as impaired and are generally considered satisfactory for the species when stormwater is not involved.

In summary, population declines and degradation of habitat for the rush darter are ongoing despite the protection afforded by State and Federal laws and corresponding regulations. Despite these laws, sedimentation and non-point source pollution continue to adversely affect the species. Because of the vulnerability of the small remaining populations of the rush darter and the imminence of these threats, we find the inadequacy of existing regulatory mechanisms to be a significant threat of high magnitude. Further, the information available to us at this time does not indicate that the magnitude or imminence of this threat is likely to be appreciably reduced in the foreseeable future.

Yellowcheek Darter

The Arkansas Department of Environmental Quality (ADEQ) has established water quality standards for surface waters in Arkansas, including specific standards for those streams designated as "extraordinary resource waters" (ERW) based on "a combination of the chemical, physical, and biological characteristics of a waterbody and its watershed, which is characterized by

scenic beauty, aesthetics, scientific values, broad scope recreation potential, and intangible social values" (ADEQ Regulation 2, November 25, 2007). As described in ADEQ's Regulation 2, Section 2.203, ERW "shall be protected by (1) water quality controls, (2) maintenance of natural flow regime, (3) protection of in stream habitat, and (4) pursuit of land management protective of the watershed." This regulatory mechanism has precluded most large scale commercial gravel mining in the watershed; however, illegal gravel mining is still considered a cause of habitat degradation and a threat in the Little Red River watershed. The Middle, Archey, and Devils (and its major tributaries) forks are designated as ERW. The South Fork has not been designated as an ERW. The applicable water quality standards have not protected yellowcheek darter habitat from the damaging habitat alterations and water quality degradation from traditional land use and expanding natural gas development activities.

The Arkansas Forestry Commission is the State agency responsible for establishing Best Management Practices (BMPs) for timber harvests in Arkansas. BMPs for timber harvests in Arkansas are only recommendations. There is no requirement that timber harvesters include BMPs in timber operations. The BMPs are currently under revision, but the Service does not know what effect these revisions will have on aquatic habitats within the range of the species.

Natural gas production in the upper Little Red River watershed presents a unique problem for yellowcheek darter conservation. In Arkansas, mineral rights for properties supersede the surface rights. Even where private landowners agree to implement certain BMPs or conservation measures on their lands for yellowcheek darter conservation, there is no guarantee that these BMPs or conservation measures will be implemented by natural gas companies, their subsidiaries, or contractors that lease and develop the mineral rights for landowners. For this reason, the intended benefits of conservation measures agreed to by landowners in agreements such as Candidate Conservation Agreements with Assurances may never be realized. Additionally, natural gas projects often do not contain a Federal nexus that would allow the Service to comment on proposed or ongoing projects.

The Arkansas Natural Resources Commission regulates water withdrawal in Arkansas streams. To date, they have not precluded water withdrawal for natural gas development activities in the upper Little Red River watershed. The U.S. Army Corps of Engineers regulates instream activities under the Clean Water Act. Their policy to date has been to issue permits for instream activities associated with pipeline construction and maintenance under Nationwide Permits rather than Individual Permits that require more public involvement. ADEQ lacks resources necessary to enforce existing regulations under the Clean Water Act and Arkansas Water and Air Pollution Act for activities associated with natural gas development.

The yellowcheek darter receives incidental protection under the Act due to the coexistence of the federally endangered speckled pocketbook mussel (*Lampsilis streckeri*), which occurs throughout the upper Little Red River drainage.

In summary, the threats of inadequacy of existing regulatory mechanisms are imminent and considered high in magnitude. This is of particular concern in regard to the vulnerability of the species to threats from natural gas development which is already impacting populations in the South and Middle forks of the Little Red River and is expected to intensify in the next several years throughout the range of the species. Further, the information available to us at this time does not indicate that the magnitude or imminence of this threat is likely to be appreciably reduced in the foreseeable future.

Chucky Madtom

The chucky madtom and its habitats are afforded some protection from water quality and habitat degradation under the Clean Water Act and TDEC's Division of Water Pollution Control under the TWQCA. However, as demonstrated under Factor A, population declines and degradation of habitat for this species are ongoing despite the protection afforded by these laws. While these laws have resulted in improved water quality and stream habitat for aquatic life, including the Chucky madtom, they alone have not been adequate to fully protect this species; sedimentation and non-point source pollutants continue to be a significant problem. Sediment is the most abundant pollutant in the Little Chucky Creek watershed and is the greatest threat to the Chucky madtom.

Portions of the Nolichucky River and its tributaries in Greene County, Tennessee, are listed as impaired (303d) by the State of Tennessee due to pasture grazing, irrigated crop production, unrestricted cattle access, land development, municipal point source discharges, septic tank failures, gravel mining, agriculture, and channelization (Tennessee Department of Environment and Conservation (TDEC) 2008, pp. 62–70). However, Little Chucky Creek is not listed as "an impaired water" by the State of Tennessee (TDEC 2008, pp. 62–70). For water bodies on the 303(d) (impaired) list, States are required under the Clean Water Act to establish a TMDL for the pollutants of concern that will bring water quality into the applicable standard. The Tennessee Department of Environment and Conservation has developed TMDLs for the Nolichucky River watershed to address the problems of fecal coliform loads, siltation, and habitat alteration by agriculture.

The chucky madtom receives incidental protection under the Act due to the coexistence of the Federally endangered Cumberland bean (*Villosa trabalis*), which is still thought to occur in Little Chucky Creek, Greene County, Tennessee (Ahlstedt 2008, pers. comm.).

The chucky madtom was listed as Endangered by the State of Tennessee in September of 2000. Under the Tennessee Nongame and Endangered or Threatened Wildlife Species Conservation Act of 1974 (Tennessee Code Annotated §§ 70-8-101-112), "[I]t is unlawful for any person to take, attempt to take, possess, transport, export, process, sell or offer for sale or ship nongame wildlife, or for any common or contract carrier knowingly to transport or receive for shipment nongame wildlife." Further, regulations included in the Tennessee Wildlife Resources Commission Proclamation 00-15 Endangered Or Threatened Species state the following: "Except as provided for in Tennessee Code Annotated, Section 70-8-106 (d) and (e), it shall be unlawful for any person to take, harass, or destroy wildlife listed as threatened or endangered or otherwise to violate terms of Section 70-8-105 (c) or to destroy knowingly the habitat of such species without due consideration of alternatives for the welfare of the species listed in (1) of this proclamation, or (2) the United States list of Endangered fauna." Under these regulations, potential collectors of this species are required to have a State collection permit. However, in terms of project management, this regulation only provides for the consideration of alternatives, and does not require the level of project review afforded by the Act.

In summary, population declines and degradation of habitat for the chucky madtom are ongoing despite the protection afforded by State and Federal laws and corresponding regulations. Despite these laws, sedimentation and

non-point source pollution continue to adversely affect the species. Because of the vulnerability of the small remaining populations of the chucky madtom and the imminence of these threats, we find the inadequacy of existing regulatory mechanisms to be a significant threat of high magnitude. Further, the information available to us at this time does not indicate that the magnitude or imminence of this threat is likely to be appreciably reduced in the foreseeable future.

Laurel Dace

The laurel dace and its habitats are afforded some protection from water quality and habitat degradation under the Clean Water Act and by TDEC's Division of Water Pollution Control under the TWQCA. However, as demonstrated under Factor A, population declines and degradation of habitat for this species are ongoing despite the protection afforded by these laws. While these laws have resulted in improved water quality and stream habitat for aquatic life, including the laurel dace, they alone have not been adequate to fully protect this species; sedimentation and non-point source pollutants continue to be a significant problem. Sediment is the most abundant pollutant in the watershed and one of the greatest threat to the laurel dace.

The State of Tennessee maintains water-use classifications through issuance of NPDES permits to industries, municipalities, and others that set maximum limits on certain pollutants or pollutant parameters. For water bodies on the 303(d) list, States are required under the Clean Water Act to establish a TMDL for the pollutants of concern that will bring water quality into the applicable standard. The Tennessee Department of Environment and Conservation has not identified any impaired water bodies in the Soddy Creek, the Sale Creek system, or the Piney River system (TDEC 2008).

The TWRA lists the laurel dace as endangered. Under the Tennessee Nongame and Endangered or Threatened Wildlife Species Conservation Act of 1974 (Tennessee Code Annotated §§ 70-8-101-112), "[I]t is unlawful for any person to take, attempt to take, possess, transport, export, process, sell or offer for sale or ship nongame wildlife, or for any common or contract carrier knowingly to transport or receive for shipment nongame wildlife." Further, regulations included in the Tennessee Wildlife Resources Commission Proclamation 00-15 Endangered Or Threatened Species state the following: "Except as provided for in Tennessee Code Annotated, Section 70-8-106 (d) and (e), it shall be unlawful for any person to take, harass, or destroy wildlife listed as threatened or endangered or otherwise to violate terms of Section 70-8-105 (c) or to destroy knowingly the habitat of such species without due consideration of alternatives for the welfare of the species listed in (1) of this proclamation, or (2) the United States list of Endangered fauna." Under these regulations, potential collectors of this species are required to have a State collection permit. However, in terms of project management, this regulation only provides for the consideration of alternatives, and does not require the level of project review afforded by the Act.

In summary, population declines and degradation of habitat for the laurel dace are ongoing despite the protection afforded by State and Federal water quality laws. While these laws have resulted in improved water quality and stream habitat for aquatic life, including the laurel dace, they alone have not been adequate to fully protect this species; sedimentation and non-point source pollutants continue to be a significant problem. Non-point pollution is not regulated by the Clean Water Act. Due to the vulnerability of the laurel dace, we find the threat of inadequate regulatory mechanisms to be imminent and of high magnitude. Further, the information available to us at this time does not indicate that the magnitude or imminence of this threat is likely to be appreciably reduced in the foreseeable future.

E. Other Natural or Manmade Factors Affecting Its Continued Existence

The Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace have limited geographic ranges and small population sizes. Their existing populations are extremely localized, and geographically isolated from one another, leaving them vulnerable to localized extinctions from intentional or accidental toxic chemical spills, habitat modification, progressive degradation from runoff (non-point source pollutants), natural catastrophic changes to their habitat (e.g., flood scour, drought), other stochastic disturbances, and to decreased fitness from reduced genetic diversity. Potential sources of unintentional spills include accidents involving vehicles transporting chemicals over road crossings of streams inhabited by one of these five fish, or the accidental or intentional release into streams of chemicals used in agricultural or residential applications.

Species that are restricted in range and population size are more likely to suffer loss of genetic diversity due to genetic drift, potentially increasing their susceptibility to inbreeding depression, decreasing their ability to adapt to environmental changes, and reducing the fitness of individuals (Soule 1980, pp. 157–158; Hunter 2002, pp. 97–101; Allendorf and Luikart 2007, pp. 117–146). It is likely that some of the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace populations are below the effective population size required to maintain long-term genetic and population viability (Soule 1980, pp. 162–164; Hunter 2002, pp. 105–107). The long-term viability of a species is founded on the conservation of numerous local populations throughout its geographic range (Harris 1984, pp. 93–104). These separate populations are essential for the species to recover and adapt to environmental change (Noss and Cooperrider 1994, pp. 264–297; Harris 1984, pp. 93–104). The level of isolation seen in these five species makes natural repopulation following localized extirpations virtually impossible without human intervention.

Climate change has the potential to increase the vulnerability of the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace to random catastrophic events (e.g., McLaughlin *et al.* 2002; Thomas *et al.* 2004). Climate change is expected to result in increased frequency and duration of droughts and the strength of storms (e.g., Cook *et al.* 2004). During 2007, a severe drought affected the upper Cumberland River basin in Kentucky and Tennessee. Streamflow values for the Cumberland River at Williamsburg, Kentucky (USGS Station Number 03404000), in September and October of 2007 were among the lowest recorded monthly values (99th percentile for low-flow periods) during the last 67 years (Cinotto 2008, pers. comm.). Climate change could intensify or increase the frequency of drought events, such as the one that occurred in 2007. Thomas *et al.* (2009, p. 112) report that the frequency, duration, and intensity of droughts are likely to increase in the southeast as a result of global climate change.

Fluker *et al.* (2007, p. 10) reported that drought conditions, coupled with rapid urbanization in watersheds that contain rush darters, render the populations vulnerable, especially during the breeding season when they concentrate in wetland pools and shallow pools of headwater streams. Drought conditions from 2006 to 2007 greatly reduced spawning habitat for

rush darter in Jefferson County (Drennen 2007, pers. obs.). Survey numbers for the rush darter within the spring-fed headwaters for the unnamed tributary to Turkey Creek during 2007 were reduced due to a lack of water (Kuhajda 2008, pers. comm.). In Winston County, Stiles and Mills (2008, pp. 5–6) noted that Doe Branch almost completely dried up during the summer of 2007. (Stiles 2008, pers. comm.).

The federally endangered watercress darter (*Etheostoma nuchale*) was translocated outside of its native range by the Service into Tapawingo Springs in 1988 in order to assist in the species, recovery by expanding its range (Moss 1995, p. 5). The watercress darter is now reproducing and may be competing with rush darters in Tapawingo Springs (USFWS 1993, p. 1; Drennen 2004, pers. obs.). More recently, a population of watercress darters was found in the Penny Springs site (Stiles and Blanchard 2001, p. 3). We require further investigation to determine whether interspecific competition is occurring between the watercress darter and the rush darter at this site. (Stiles 2008, pers. comm.).

The Little Red River watershed in Arkansas experienced moderate drought conditions during 1997-2000 (Southern Regional Climate Center 2000), which reduced flows in its tributaries and affected yellowcheek darter populations. Stage height was 1 foot lower during the sampling period for the 2000 status survey than during the 1979–1980 study (Wine *et al.* 2000, p. 7). Stream flow is strongly correlated with important physical and chemical parameters that limit the distribution and abundance of riverine species (Power *et al.* 1995, p. 159, Resh *et al.* 1988, p. 437) and regulates the ecological integrity of flowing water systems (Poff *et al.* 1997, p. 769). Yellowcheek darter was not found in the upper reaches of any study streams or in the Turkey/Beech Fork reach of Devils Fork, a likely result of drought conditions, and indicates a contraction of yellowcheek darter range to stream reaches lower in the watershed where flows are maintained for a greater portion of the year (Wine *et al.* 2000, p. 11). The threat immediacy and magnitude of drought is imminent and moderate to high, respectively, in all four watersheds for the yellowcheek darter. Exacerbation of natural drought cycles as a result of global climate change could have detrimental effects on the species which could continue for the foreseeable future.

The low fecundity rates exhibited by many madtom catfishes (Breder and Rosen 1966 *in* Dinkins and Shute 1996, p. 58) could limit the potential for populations to rebound from disturbance events. The short life span exhibited by members of the *N. hildebrandi* clade (a taxonomic group of organisms classified together on the basis of homologous features traced to a common ancestor) of madtoms, if also true of chucky madtoms, would further limit the species' viability by rendering it vulnerable to severe demographic shifts from disturbances that prevent reproduction in even a single year, and could be devastating to the population if the disturbance persists for successive years.

In summary, because the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace all have limited geographic ranges and small population sizes, they are subject to several ongoing natural and manmade threats. Since these threats are ongoing, they are considered to be imminent. Exacerbation of natural drought cycles as a result of global climate change could have detrimental effects on these five species which is expected to continue or increase in the future. The magnitude of these threats is high for each of these species because of their reduced ranges and population sizes which result in a reduced ability to adapt to environmental change. Further, the information available to us at this time does not indicate that the magnitude or imminence of this threat is likely to be appreciably reduced in the foreseeable future.

Proposed Determination

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace. Based on the immediate and ongoing significant threats to these species throughout their entire ranges, as described above in the five-factor analyses, we consider these species to be in danger of extinction throughout all of their ranges. The Endangered Species Act (Sec. 3(5)(C)(6)) defines an endangered species as "any species which is in danger of extinction throughout all or a significant portion of its range." Therefore, on the basis of the best available scientific and commercial information, we are proposing to list these five fishes as endangered species, in accordance with Section 4(a)(1) of the Act.

The Cumberland darter is threatened with range curtailment, specifically its disappearance from 9 streams and 11 historic sites, and its small population size (only 51 individuals observed during the most recent surveys by Thomas (2007, p. 3)). Rush darter populations are isolated from each other, and individual rush darters are only sporadically collected within their range. Where it occurs, the rush darter is an uncommon species that is usually collected in low numbers. Yellowcheek darter populations are restricted to portions of four headwater streams, have declined drastically over the last 30 years and are effectively isolated as a result of reservoir construction. Only three specimens of the chucky madtom have been encountered since 2000 (one in 2000 and two in 2004), despite several surveys that have been conducted in Little Chucky Creek and several streams in the Nolichucky, Holston, and French Broad River watersheds of the upper Tennessee River basin, which are similar in size and character to Little Chucky Creek. The laurel dace is restricted to six streams, where they are only known to occupy reaches of approximately 0.3 to 8 km (0.2 to 5 mi) in length. These isolated species have a limited ability to recolonize historically occupied stream and river reaches and are vulnerable to natural or human-caused changes in their stream and river habitats. Their range curtailment, small population size, and isolation make these five species more vulnerable to threats such as sedimentation, disturbance of riparian corridors, changes in channel morphology, point and non-point source pollutants, urbanization, and introduced species.

Therefore, as described above, these five species are in danger of extinction throughout their highly localized ranges due to their reduction of habitat and ranges, small population sizes, current habitat threats, and resulting vulnerability due to lack of regulatory mechanisms and natural or human induced catastrophic events. Efforts to control excessive sedimentation and improve general water quality throughout their ranges coupled with efforts to increase population levels will be essential for these species' survival.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing encourages and results in public awareness and conservation by Federal, State, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and requires that recovery actions be carried out for

all listed species. The protection required of Federal agencies and the prohibitions against take and harm are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Subsection 4(f) of the Act requires the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed, preparation of a draft and final recovery plan, and revisions to the plan as significant new information becomes available. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. The recovery plan identifies site-specific management actions that will achieve recovery of the species, measurable criteria that determine when a species may be downlisted or delisted, and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (comprised of species experts, Federal and State agencies, non-government organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our website (*http://www.fws.gov/endangered*), or from our Fish and Wildlife Service Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribal, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (e.g., restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

Listing will also require the Service to review any actions on Federal lands and activities under Federal jurisdiction that may adversely affect the five species; allow State plans to be developed under section 6 of the Act; encourage scientific investigations of efforts to enhance the propagation or survival of the animals under section 10(a)(1)(A) of the Act; and promote habitat conservation plans on non-Federal lands and activities under section 10(a)(1)(B) of the Act.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Federal agencies are required to confer with us informally on any action that is likely to jeopardize the continued existence of a proposed species. Section 7(a)(4) requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may adversely affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service.

Federal activities that may affect the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace include, but are not limited to, the funding, carrying out, or the issuance of permits for reservoir construction, natural gas extraction, stream alterations, discharges, wastewater facility development, water withdrawal projects, pesticide registration, mining, and road and bridge construction.

Jeopardy Standard

Prior to and following listing and designation of critical habitat, if prudent and determinable, the Service applies an analytical framework for jeopardy analyses that relies heavily on the importance of core area populations to the survival and recovery of the species. The section 7(a)(2) analysis is focused not only on these populations but also on the habitat conditions necessary to support them.

The jeopardy analysis usually expresses the survival and recovery needs of the species in a qualitative fashion without making distinctions between what is necessary for survival and what is necessary for recovery. Generally, if a proposed Federal action is incompatible with the viability of the affected core area populations(s), inclusive of associated habitat conditions, a jeopardy finding is considered to be warranted, because of the relationship of each core area population to the survival and recovery of the species as a whole.

Section 9 Take

Section 9(a)(2) of the Act, and its implementing regulations found at 50 CFR 17.21, set forth a series of general prohibitions and exceptions that apply to all endangered wildlife. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to take (includes harass, harm, pursue, hunt, shoot, wound, kill, trap, or collect, or to attempt any of these), import or export, ship in interstate commerce in the course of commercial activity, or sell or offer for sale in interstate or foreign commerce any listed species. It also is illegal to knowingly possess, sell, deliver, carry, transport, or ship any wildlife that has been taken illegally. Certain exceptions apply to agents of the Service and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving endangered wildlife species under certain circumstances. Regulations governing permits are at 50 CFR 17.22 for endangered species. Such permits are available for scientific purposes, to enhance the propagation or survival of the species or for incidental take in connection with otherwise lawful activities. The yellowcheek darter is currently covered under a joint Safe Harbor/Candidate Conservation Agreement with Assurances (SHA/CCAA) in the upper Little Red River watershed in Arkansas along with the endangered speckled pocketbook mussel. Seven landowners have enrolled 3,845 hectares (9,500 acres) in the program since its inception in mid-2007 and 10 more landowners with approximately 19, 420 hectares (48,000 acres) are pending with draft agreements. The CCAA would convert to a SHA if the species becomes listed as threatened or endangered and would be covered by an enhancement of

survival permit, which expires January 1, 2044.

Under the Interagency Cooperative Policy for Endangered Species Act Section 9 Prohibitions, published in the **Federal Register** on July 1, 1994 (59 FR 34272), we identify to the maximum extent practicable those activities that would or would not constitute a violation of section 9 of the Act if the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace are listed. The intent of this policy is to increase public awareness as to the effects of these proposed listings on future and ongoing activities within a species' range. We believe, based on the best available information, that the following actions will not result in a violation of the provisions of section 9 of the Act, provided these actions are carried out in accordance with existing regulations and permit requirements:

(1) Possession, delivery, or movement, including interstate transport that does not involve commercial activity, of specimens of these species that were legally acquired prior to the publication in the **Federal Register** of the Federal List of Endangered or Threatened Wildlife and Plants;

(2) Discharges into waters supporting the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace, provided these activities are carried out in accordance with existing regulations and permit requirements (e.g., activities subject to section 404 of the Clean Water Act and discharges regulated under the National Pollutant Discharge Elimination System (NPDES));

(3) Development and construction activities designed and implemented under State and local water quality regulations and implemented using approved Best Management Practices; and

(4) Any actions that may affect the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace that are authorized, funded, or carried out by a Federal agency (e.g., bridge and highway construction, pipeline construction, hydropower licensing, etc.), when the action is conducted in accordance with the consultation and planning requirements for listed species pursuant to sections 7 and 10 of the Act.

Potential activities that we believe will likely be considered a violation of section 9 if these species become listed, include, but are not limited to, the following:

(1) Unauthorized possession, collecting, trapping, capturing, killing, harassing, sale, delivery, or movement, including interstate and foreign commerce, or harming, or attempting any of these actions, of the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace;

(2) Unlawful destruction or alteration of their habitats (e.g., unpermitted instream dredging, impoundment, channelization, discharge of fill material) that impairs essential behaviors such as breeding, feeding, or sheltering, or results in killing or injuring any of these species;

(3) Violation of any discharge or water withdrawal permit that results in harm or death to any of these species or that results in degradation of their occupied habitat to an extent that essential behaviors such as breeding, feeding and sheltering are impaired; and

(4) Unauthorized discharges or dumping of toxic chemicals or other pollutants into waters supporting the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace that kills or injures these species, or otherwise impairs essential life-sustaining requirements such as breeding, feeding, or shelter.

Other activities not identified above will be reviewed on a case-by-case basis to determine if a violation of section 9 of the Act may be likely to result from such activity should these fishes become listed. The Service does not consider these lists to be exhaustive and provides them as information to the public.

If you have questions regarding whether specific activities will likely violate the provisions of section 9 of the Act, contact the Alabama, Arkansas, Tennessee, Kentucky, or Mississippi Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT** section). Requests for copies of regulations regarding listed species and inquiries about prohibitions and permits should be addressed to the U.S. Fish and Wildlife Service, Ecological Services Division, 1875 Century Boulevard, Atlanta, GA 30345 (Phone 404/679-7313; Fax 404/679-7081).

Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(i) the specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(I) essential to the conservation of the species, and

(II) that may require special management considerations or protection; and

(ii) specific areas outside the geographic area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary.

Critical habitat receives protection under section 7 of the Act through the prohibition against Federal agencies carrying out, funding, or authorizing the destruction or adverse modification of critical habitat. Section 7(a)(2) requires consultation on Federal actions that may affect critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner seeks or requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the consultation requirements of section 7(a)(2) of the Act would apply, but even in the event of a destruction or adverse modification finding, the obligation of the Federal action agency and the applicant is not to restore or recover the species, but to implement reasonable and prudent alternatives to avoid destruction or adverse modification of critical habitat.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12), require that, to the maximum extent prudent and determinable, we designate critical habitat at the time the species is determined to be endangered or threatened. Our regulations (50 CFR 424.12(a)(1)) state that the designation of critical habitat is not prudent when one or both of the following situations exist: (1) The species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species, or (2) such designation of critical habitat would not be beneficial to the species.

There is no documentation that the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, or laurel dace are threatened by taking or

other human activity such that identification of critical habitat for each of these species could be expected to increase the degree of threat to them. In the absence of finding that the designation of critical habitat would increase threats to a species, if there are any benefits to a critical habitat designation, then we would determine that the designation of critical habitat is prident. For these species, the potential benefits include: (1) Triggering consultation under section 7 of the Act, in new areas for actions in which there may be a Federal nexus where it would not otherwise occur because, for example, it is or has become unoccupied or the occupancy is in question; (2) focusing conservation activities on the most essential features and areas; (3) providing educational benefits to State or county governments, private entities, and the public as a whole; and (4) preventing people from causing inadvertent harm to the species.

The primary regulatory effect of critical habitat is the section 7(a)(2) requirement that Federal agencies refrain from taking any action that destroys or adversely affects critical habitat. Extant populations of the Cumberland darter occur in watersheds that are roughly 60 percent privately owned and 40 percent publicly-owned (U.S. Forest Service (USFS), DBNF). The U.S. Forest Service's ownership is typically fragmented and often occurs on only one side of the stream. The rush darter occupies streams that are approximately 96 percent privately owned industrial, forestry, agricultural, and urbanized lands. The State of Alabama, Jefferson County, and the Freshwater Land Trust own and maintain about two percent of the rush darter's habitat; and the USFS manages approximately two percent of habitat in the Bankhead National Forest. The U.S. Forest Service owns two percent of yellowcheek darter habitat in Arkansas, while the Arkansas Game and Fish Commission owns one percent. The remaining 97 percent is privately owned. In the Little Chucky Creek watershed, the chucky madtom occupies habitat that is primarily privately owned. Approximately five percent of the Dunn Creek watershed is owned by the National Park Service (i.e., portions of the Great Smoky Mountains National Park and Foothills Parkway), but the majority of the watershed is privately owned habitat for the madtom. The laurel dace is only known to occur in waters within privately owned lands. Any of the abovementioned lands that may be designated as critical habitat in the future for these species may be subject to Federal actions that trigger the section 7 consultation requirement, such as the granting of Federal monies for conservation projects and/or the need for Federal permits for projects (e.g., construction and maintenance of roads and bridges subject to section 404 of the Clean Water Act).

There may also be some educational or informational benefits to the designation of critical habitat. Educational benefits include the notification of land owners, land managers, and the general public of the importance of protecting the habitat of these species. In the case of these species, this aspect of critical habitat designation would potentially benefit the conservation of these species.

Therefore, since we have determined that the designation of critical habitat will not likely increase the degree of threat to the species and may provide some measure of benefit, we find that designation of critical habitat is prudent for the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace.

Critical Habitat Determinability

As stated above, section 4(a)(3) of the Act requires the designation of critical habitat concurrently with the species' listing "to the maximum extent prudent and determinable." Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

(i) Information sufficient to perform required analyses of the impacts of the designation is lacking, or

(ii) The biological needs of the species are not sufficiently well known to permit identification of an area as critical habitat.

When critical habitat is not determinable, the Act provides for an additional year to publish a critical habitat designation (16 U.S.C. 1533(b)(6)(C)(ii)).

In accordance with section 3(5)(A)(i) and 4(b)(1)(A) of the Act and the regulations at 50 CFR 424.12, in determining which areas occupied by the species at the time of listing to designate as critical habitat, we consider the physical and biological features essential to the conservation of the species which may require special management considerations or protection. These include, but are not limited to:

(1) Space for individual and population growth and for normal behavior;

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements;

(3) Cover or shelter;

(4) Sites for breeding, reproduction, and rearing (or development) of offspring; and

(5) Habitats that are protected from disturbance or are representative of the historical geographical and ecological distributions of a species.

We are currently unable to identify the physical and biological features for the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace, because information on the physical and biological features that are considered essential to the conservation of these species is not known at this time. As discussed in the "Species Information" section of this proposed rule, the life histories of these species are poorly known. Although, as described above, we can surmise that habitat degradation from a variety of factors has contributed to the decline of these species, we do not know specifically the essential physical or biological features the habitat is currently lacking. As we are unable to identify the physical and biological features essential to the conservation of these species, we are unable to identify areas that contain these features. Therefore, although we have determined that the designation of critical habitat is prudent for the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace, since the biological requirements of these species are not sufficiently known, we find that critical habitat for these species is not determinable at this time.

How the Service Intends to Proceed

We intend to begin preparation of proposed rulemaking in Fiscal Year 2011 and publish a proposed critical habitat designation for Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace in June 2011. We will take the following steps to develop a proposal of critical habitat for the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace: (1) Determine the geographical area occupied by the species at the time of listing; (2) identify the physical or biological features essential to the conservation of the species; (3) delineate areas within the geographical area occupied by the species that contain these features, and identify the special management considerations or protections the features may require; (4) delineate any areas outside of the geographical area occupied by the species at the time of listing that are essential for the conservation of the species; and (5) conduct appropriate analyses under section 4(b)(2) of the Act.

To aid us in completing these steps, we will use the best science available. We also solicit the public for additional information (see **Request for Public Information** section below) and will consult experts on the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace.

While the proposed designation of critical habitat for these fishes is under preparation, the areas occupied by these species in the United States will continue to be subject to conservation actions implemented under section 7(a)(1) of the Act, as well as consultation pursuant to section 7(a)(2) of the Act for Federal activities that may affect any of these species, as determined on the basis of the best available scientific information at the time of the action. In addition, the prohibition of taking Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace under section 9 of the Act (e.g., prohibitions against killing, harming, harassing, and capturing endangered species) continues to apply.

We will also continue to use our authorities to work with agencies and other partners in the to conserve and recover these species. We are working with the partners to develop and implement a framework for the conservation of the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace.

Request for Public Information

We intend that any designation of critical habitat for the Cumberland darter, rush darter, yellowcheek darter, chucky madtom, and laurel dace be as accurate as possible. Therefore, we will continue to accept additional information and comments from all concerned governmental agencies, the scientific community, industry, or any other interested party concerning this finding. We are particularly interested in information concerning:

(1)The reasons why areas should or should not be designated as critical habitat as provided by section 4 of the Act (16 U.S.C. 1531, *et seq.*), including whether the benefits of designation would outweigh threats to the species that designation could cause (e.g., exacerbation of existing threats, such as overcollection), such that the designation of critical habitat is prudent; and

(2)Specific information on:

- What areas contain physical and biological features essential for the conservation of the species;
- What areas are essential to the conservation of the species; and
- Special management considerations or protection that proposed critical habitat may require;
- Conservation programs and plans that protect these species and their habitat; and;
- Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comments.

Public Comment Procedures

To ensure that any final action resulting from this finding will be as accurate and as effective as possible, we request that you send relevant information for our consideration. The comments that will be most useful and likely to influence our decisions are those that you support by quantitative information or studies and those that include citations to, and analyses of, the applicable laws and regulations. Please make your comments as specific as possible and explain the bases for them. In addition, please include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include. For instructions on how to submit comments, please see the **Request for Public Comments**

Section.

Public Availability of Comments

As stated above in more detail, before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Peer Review

In accordance with our joint policy published in the **Federal Register** on July 1, 1994 (59 FR 34270), we will seek the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of such review is to ensure that our proposed rule is based on scientifically sound data, assumptions, and analyses. We will send these peer reviewers copies of this proposed rule immediately following publication in the **Federal Register**. We will invite these peer reviewers to comment, during the public comment period, on the specific assumptions and the data that are the basis for our conclusions regarding the proposal to list Cumberland darter (*Etheostoma susanae*), rush darter (*Etheostoma phytophilum*), yellowcheek darter (*Etheostoma moorei*), chucky madtom (*Noturus crypticus*), and laurel dace (*Phoxinus saylori*) as endangered and our proposal regarding critical habitat for this species.

We will consider all comments and information we receive during the comment period on this proposed rule during preparation of a final rulemaking. Accordingly, our final decision may differ from this proposal.

Public Hearings

The Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposal in the **Federal Register**. Such requests must be made in writing and be addressed to the Field Supervisor at the address in the **FOR FURTHER INFORMATION CONTACT** section. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Persons needing reasonable accommodations to attend and participate in a public hearing should contact the Tennessee Ecological Services Field Office by telephone at 931-528-6481, as soon as possible. To allow sufficient time to process requests, please call no later than one week before the hearing date. Information regarding this proposed rule is available in alternative formats upon request.

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES**

section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the names of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.)

This rule does not contain any new collections of information that require approval by Office of Management and Budget (OMB) under the Paperwork Reduction Act. This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A complete list of all references cited in this rule is available on the Internet at *http://www.regulations.govor* upon request from the Field Supervisor, Tennessee Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT** section).

Author(s)

The primary authors of this document are staff members of the U.S. Fish and Wildlife Service's Tennessee Ecological Services Field Office, Kentucky Ecological Services Field Office, Arkansas Ecological Services Office, and the Mississippi Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361-1407; 16 U.S.C. 1531-1544; 16 U.S.C. 4201-4245; Public Law 99-625, 100 Stat. 3500; unless otherwise noted.

2. In §17.11(h) add the following to the List of Endangered and Threatened Wildlife in alphabetical order under Fishes:

§17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*		*	*	*
FISHES							
*	*	*	*		*	*	*
Dace, laurel	*Phoxinus saylori*	U.S.A (TN)	Entire	E	TBD	NA	NA
*	*	*	*		*	*	*
Darter, Cumberland	*Etheostoma susanae*	U.S.A. (KY, TN)	Entire	E	TBD	NA	NA
*	*	*	*		*	*	*
Darter, rush	*Etheostoma phytophilum*	U.S.A. (AL)	Entire	E	TBD	NA	NA
*	*	*	*		*	*	*
Darter, yellowcheek	*Etheostoma moorei*	U.S.A. (AR)	Entire	E	TBD	NA	NA
*	*	*	*		*	*	*
Madtom, chucky	*Noturus crypticus*	U.S.A. (TN)	Entire	E	TBD	NA	NA
*	*	*	*		*	*	*

* * * * *

Dated: June 2, 2010

Jeffrey L. Underwood,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2010–15240 Filed 6–23– 10; 8:45 am]

BILLING CODE 4310–55–S

Notices

Federal Register

Vol. 75, No. 121

Thursday, June 24, 2010

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–FV–10–0034; FV10–901–1NC]

Notice of Request for Extension and Revision of a Currently Approved Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces the Agricultural Marketing Service's (AMS) intention to request an extension for and revision to a currently approved generic information collection for vegetables and specialty crop marketing order programs.

DATES: Comments on this notice must be received by August 23, 2010 to be assured of consideration.

Additional Information or Comments: Contact Andrew Hatch, Supervisory Marketing Specialist, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Room 1406–S, Washington, DC 20250–0237; Telephone: (202) 720–6862, Fax: (202) 720–8938, or E-mail: *Andrew.hatch@ams.usda.gov.*

Small businesses may request information on this notice by contacting Antoinette Carter, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Room 1406–S, Washington, DC 20250–0237; Telephone (202) 690–3919, Fax: (202) 720–8938, or E-mail: *antoinette.carter@ams.usda.gov.*

Comments: Comments should reference the document number and the date and page number of this issue of the **Federal Register,** and be mailed to the Docket Clerk, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., Room 1406–S, Washington, DC 20250–0237; Fax: (202) 720–8938); or submitted through the Internet at *http://www.regulations.gov.*

SUPPLEMENTARY INFORMATION:

Title: Vegetable and Specialty Crop Marketing Orders.

OMB Number: 0581–0178.

Expiration Date of Approval: February 28, 2011.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: Marketing order programs provide an opportunity for producers of fresh fruit, vegetables, and specialty crops, in specified production areas, to work together to solve marketing problems that cannot be solved individually. This notice covers the following marketing order program citations: 7 CFR parts 932 (California olives), 945 (Idaho/Oregon potatoes), 946 (Washington potatoes), 947 (Oregon/California potatoes), 948 (Colorado potatoes), 953 (North Carolina/Virginia potatoes), 955 (Vidalia onions), 956 (Walla Walla onions), 958 (Idaho/Oregon onions), 959 (South Texas onions), 966 (Florida tomatoes), 981 (California almonds), 982 (Oregon/Washington hazelnuts), 984 (California walnuts), 985 (Northwest spearmint oil), 987 (California dates), 989 (California raisins), 993 (California prunes), and 999 (Specialty Crop Import Regulation). Order regulations help ensure adequate supplies of high quality products for consumers and adequate returns to producers. Under the Agricultural Marketing Agreement Act of 1937 (Act), as amended (7 U.S.C. 601–674), industries enter into marketing order programs. The Secretary of Agriculture (Secretary) is authorized to oversee the order operations and issue regulations recommended by a committee or board of representatives from each commodity industry.

The information collection requirements in this request are essential to carry out the intent of the Act, to provide the respondents the type of service they request, and to administer the marketing order programs. Under the Act, orders may authorize the following: Production and marketing research including paid advertising, volume regulations, reserves, including pools and producer allotments, container regulations, and quality control. Assessments are levied on handlers regulated under the marketing orders. Also pursuant to Section 8e of the Act, importers of raisins, dates, and dried prunes are required to submit certain information.

USDA requires several forms to be filed in order to enable the administration of each marketing order program. These include forms covering the selection process for industry members to serve on a marketing order's committee or board and ballots used in referenda to amend or continue marketing order programs.

Under Federal marketing orders, producers and handlers are nominated by their peers to serve as representatives on a committee or board which administers each program. Nominees must provide information on their qualifications to serve on the committee or board. Nominees are selected by the Secretary. Formal rulemaking amendments must be approved in referenda conducted by USDA and the Secretary. For the purposes of this action, ballots are considered information collections and are subject to the Paperwork Reduction Act. If an order is amended, handlers are asked to sign an agreement indicating their willingness to abide by the provisions of the amended order.

Some forms are required to be filed with the committee or board. The orders and their rules and regulations authorize the respective commodities' committees and boards, the agencies responsible for local administration of the orders, to require handlers and producers to submit certain information. Much of the information is compiled in aggregate and provided to the respective industries to assist in marketing decisions. The committees and boards have developed forms as a means for persons to file required information relating to supplies, shipments, and dispositions of their respective commodities, and other information needed to effectively carry out the purpose of the Act and their respective orders, and these forms are utilized accordingly.

The forms covered under this information collection require the minimum information necessary to effectively carry out the requirements of the orders, and their use is necessary to fulfill the intent of the Act as expressed

in the orders, and the rules and regulations issued under the orders.

The information collected is used only by authorized employees of the committees and boards and authorized representatives of the USDA, including AMS, Fruit and Vegetable Programs' regional and headquarters' staff. Authorized committee/board employees are the primary users of the information and AMS is the secondary user.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.10 hours per response.

Respondents: Producers, handlers, processors, dehydrators, cooperatives, manufacturers, importers, and public members.

Estimated Number of Respondents: 20,626.

Estimated Number of Total Annual Responses: 174,142.

Estimated Number of Responses per Respondent: 8.47

Estimated Total Annual Burden on Respondents: 17,498.50 hours.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record. All comments received will be available for public inspection at the street address in the "Comment" section and can be viewed at: *http://www.regulations.gov.*

Dated: June 18, 2010.

David R. Shipman,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2010–15297 Filed 6–23–10; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–FV–10–0033; FV10–902–1NC]

Notice of Request for Extension and Revision of a Currently Approved Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces the Agricultural Marketing Service's (AMS) intention to request an extension and revision to a currently approved generic information collection for marketing orders covering fruit crops.

DATES: Comments on this notice must be received by August 23, 2010 to be assured of consideration.

Additional Information: Contact Andrew Hatch, Supervisory Marketing Specialist, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Room 1406–S, Washington, DC 20250–0237; Telephone: (202) 720–6862, Fax: (202) 720–8938, E-mail: *andrew.hatch@ams.usda.gov.*

Small businesses may request information on this notice by contacting Antoinette Carter, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Room 1406–S, Washington, DC 20250–0237; Telephone (202) 690–3919, Fax: (202) 720–8938, or e-mail: *antoinette.carter@ams.usda.gov.*

Comments: Comments should reference the document number and the date and page number of this issue of the **Federal Register**, and be mailed to the Docket Clerk, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., Room 1406–S, Washington, DC 20250–0237; Fax: (202) 720–8938); or submitted through the Internet at *http://www.regulations.gov.*

SUPPLEMENTARY INFORMATION:

Title: Marketing Orders for Fruit Crops.

OMB Number: 0581–0189.

Expiration Date of Approval: November 30, 2010.

Type of Request: Extension and Revision of a currently approved information collection.

Abstract: Marketing order programs provide an opportunity for producers of fresh fruits, vegetables and specialty crops, in specified production areas, to work together to solve marketing problems that cannot be solved individually. This notice covers the following marketing order program citations 7 CFR parts 905 (Florida citrus), 906 (Texas citrus), 915 (Florida avocados), 916 (California nectarines), 917 (California peaches and pears), 920 (California kiwifruit), 922 (Washington apricots), 923 (Washington cherries), 924 (Oregon/Washington prunes), 925 (California table grapes), 927 (Oregon/Washington pears), and 929 (Cranberries grown in 10 States). Order regulations help ensure adequate supplies of high quality product and adequate returns to producers. Under the Agricultural Marketing Agreement Act of 1937 (Act), as amended (7 U.S.C. 601–674) industries enter into marketing order programs. The Secretary of Agriculture is authorized to oversee the order operations and issue regulations recommended by a committee of representatives from each commodity industry.

The information collection requirements in this request are essential to carry out the intent of the Act, to provide the respondents the type of service they request, and to administer the marketing order programs. Under the Act, orders may authorize the following: Production and marketing research, including paid advertising; volume regulations; reserves, including pools and producer allotments; container regulations; and quality control. Assessments are levied on handlers regulated under the marketing orders.

USDA requires several forms to be filed to enable the administration of each marketing order program. These include forms covering the selection process for industry members to serve on a marketing order's committee or board and ballots used in referenda to amend or continue marketing order programs.

Under Federal marketing orders, producers and handlers are nominated by their peers to serve as representatives on a committee or board which administers each program. Nominees must provide information on their qualifications to serve on the committee or board. Nominees are appointed by the Secretary. Formal rulemaking amendments must be approved in referenda conducted by USDA and the Secretary. For the purposes of this action, ballots are considered information collections and are subject to the Paperwork Reduction Act. If an order is amended, handlers are asked to sign an agreement indicating their

willingness to abide by the provisions of the amended order.

Some forms are required to be filed with the committee or board. The orders and their rules and regulations authorize the respective commodities' committees and boards, the agencies responsible for local administration of the orders, to require handlers and producers to submit certain information. Much of the information is compiled in aggregate and provided to the respective industries to assist in marketing decisions. The committees and boards have developed forms as a means for persons to file required information relating to supplies, shipments, and dispositions of their respective commodities, and other information needed to effectively carry out the purpose of the Act and their respective orders, and these forms are utilized accordingly.

The forms covered under this information collection require the minimum information necessary to effectively carry out the requirements of the orders, and their use is necessary to fulfill the intent of the Act as expressed in the orders rules and regulations.

The information collected is used only by authorized employees of the committees and authorized representatives of the USDA, including AMS, Fruit and Vegetable Programs' regional and headquarters' staff. Authorized committee or board employees are the primary users of the information and AMS is the secondary user.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .28 hours per response.

Respondents: Producers, handlers, processors, cooperatives, and public members.

Estimated Number of Respondents: 16,043.

Estimated Number of Responses: 30,604.

Estimated Number of Responses per Respondent: 1.91.

Estimated Total Annual Burden on Respondents: 8,419 hours.

Comments are invited on: (1) Whether the proposed collection of the information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record. All comments received will be available for public inspection at the street address in the "Comment" section and can be viewed at: *http://www.regulations.gov.*

Dated: June 18, 2010.

David R. Shipman,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2010–15300 Filed 6–23–10; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2010-0044]

Notice of Request for Extension of Approval of an Information Collection; Blood and Tissue Collection at Slaughtering and Rendering Establishments

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with regulations for blood and tissue collection at slaughtering and rendering establishments to enhance animal disease surveillance.

DATES: We will consider all comments that we receive on or before August 23, 2010.

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to (*http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2010-0044*) to submit or view comments and to view supporting and related materials available electronically.
- Postal Mail/Commercial Delivery: Please send one copy of your comment to Docket No. APHIS-2010-0044, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. APHIS-2010-0044.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at (*http://www.aphis.usda.gov*).

FOR FURTHER INFORMATION CONTACT: For information on regulations for blood and tissue collection at slaughtering and rendering establishments, contact Dr. Debra Cox, Senior Staff Veterinarian, Surveillance and Identification Programs, NCAHP, VS, APHIS, 4700 River Road Unit 200, Riverdale MD 20737; (301) 734-6954. For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

SUPPLEMENTARY INFORMATION:

Title: Blood and Tissue Collection at Slaughtering and Rendering Establishments.

OMB Number: 0579-0212.

Type of Request: Extension of approval of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, is authorized to prevent the interstate spread of livestock diseases and for eradicating such diseases from the United States when feasible. In connection with this mission, the Veterinary Services (VS) program, APHIS, conducts animal disease surveillance programs, including diagnostic testing.

The regulations in 9 CFR, subchapter C, part 71, "General Provisions," provide for the collection of blood and tissue samples from livestock (horses, cattle, bison, captive cervids, sheep and goats, swine, and other farmed animals) and poultry at slaughter. Persons moving livestock and poultry interstate for slaughter may only move the animals to slaughtering or rendering establishments that have been listed by the Administrator of APHIS. Federal personnel, in conjunction with establishment personnel, are required to

complete a listing agreement and a facility inspection report (VS Form 10-5). At APHIS' discretion, slaughtering or rendering establishment personnel will collect blood and tissue samples to assess the prevalence of disease and to identify sources of disease. The test-at-slaughter program necessitates the use of specimen submission and supplemental forms (VS Forms 10-4/10-4A). If APHIS denies or withdraws an establishment's listing, the establishment may appeal the denial or withdrawal in writing to APHIS.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; e.g., permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.250395 hours per response.

Respondents: Slaughtering and rendering establishment personnel.

Estimated annual number of respondents: 66.

Estimated annual number of responses per respondent: 162.8333.

Estimated annual number of responses: 10,747.

Estimated total annual burden on respondents: 2,691 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 17th day of June 2010.

Kevin Shea

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2010–15301 Filed 6–23–10: 8:45 am]

BILLING CODE 3410–34–S

DEPARTMENT OF AGRICULTURE

Forest Service

Humboldt Resource Advisory Committee (RAC)

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Humboldt Resource Advisory Committee (RAC) will meet in Eureka, California. The committee meeting is authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110–343) and in compliance with the Federal Advisory Committee Act. The purpose of the meeting is to orientate new committee members to the Secure Rural Schools Act, guidelines for Title II, and Federal Advisory Committees Act and receive public comment on the meeting subjects and proceedings.

DATES: The meeting will be held July 13, 2010, from 5 p.m. to 7 p.m.

ADDRESSES: The meeting will be held at the Six Rivers National Forest Office, 1330 Bayshore Way, Eureka, CA 95501.

FOR FURTHER INFORMATION CONTACT: Julie Ranieri, Committee Coordinator, Six Rivers National Forest, 1330 Bayshore Way, Eureka, CA 95503 (707) 441–3673; e-mail *jranieri@fs.fed.us.*

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Agenda items to be covered include: (1) Develop and approve operational guidelines and ground rules; (2) presentation on the National Environmental Policy Act; (3) Title II projects; (4) project solicitation process and timeline; and (5) receive public comment. An opportunity will be provided for the public to address the Committee.

Dated: June 18, 2010.

Tyrone Kelley,

Forest Supervisor.

[FR Doc. 2010–15308 Filed 6–23–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Forest Service

Snohomish County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Snohomish County Resource Advisory Committee (RAC) will meet in Everett, Washington on July 7, 2010. The committee is meeting to review and prioritize 2009/2010 Snohomish County RAC Project Proposals for funding.

DATES: The meeting will be held on Wednesday, July 7, 2010, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the Snohomish County Administration Building West in the 6th floor Executive Conference Room, located at 3000 Rockefeller Ave., Everett, Washington 98201.

FOR FURTHER INFORMATION CONTACT: Peter Forbes, District Ranger, Darrington Ranger District, phone (360) 436–2301, e-mail *pforbes@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. More information will be posted on the Mt. Baker-Snoqualmie National Forest Web site at *http://www.fs.fed.us/r6/mbs/projects/rac.shtml.*

Comments may be sent via e-mail to *pforbes@fs.fed.us* or via facsimile to (360) 436–1309. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Darrington Ranger District office at 1405 Emens Avenue, Darrington, Washington, during regular office hours (Monday through Friday 8 a.m.–4:30 p.m.).

Dated: June 16, 2010.

Y. Robert Iwamoto,

Forest Supervisor.

[FR Doc. 2010–15102 Filed 6–23–10; 8:45 am]

BILLING CODE 3410–11–M

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the North Carolina Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a meeting of the North Carolina Advisory Committee (Committee) to the Commission will convene on Wednesday, July 14, 2010,

at 1 p.m. and adjourn at approximately 4 p.m. (EST) at the International Civil Rights Center, 134 S. Elm Street, Greensboro, NC, 27401. The purpose of the meeting is for the Committee to discuss its report on disparate discipline of minority youth by public school districts.

Members of the public are entitled to submit written comments. The comments must be received in the Southern Regional Office by August 14, 2010. The mailing address is Southern Regional Office, U.S. Commission on Civil Rights, 61 Forsyth Street, Suite 18T40, Atlanta, GA 30301. Persons wishing to e-mail their comments may do so to *pminarik@usccr.gov.* Persons that desire additional information should contact Peter Minarik, Regional Director, Southern Regional Office, at (404) 562–7000 (or for hearing impaired TDD 913–551–1414).

Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

Records generated from this meeting may be inspected and reproduced at the Southern Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *http://www.usccr.gov,* or to contact the Southern Regional Office at the above e-mail or street address.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission and FACA.

Dated in Washington, DC, June 18, 2010.

Peter Minarik,

Acting Chief, Regional Programs Coordination Unit.

[FR Doc. 2010–15262 Filed 6–23–10; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Availability of Conservation Seat and Diving Operations Seat for the Flower Garden Banks National Marine Sanctuary Advisory Council

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice and request for applications.

SUMMARY: The ONMS is seeking applications for the following vacant seats on the Flower Garden Banks National Marine Sanctuary Advisory Council: Conservation and Diving Operations. Applicants are chosen based upon their particular expertise and experience in relation to the seat for which they are applying; community and professional affiliations; philosophy regarding the protection and management of marine resources; and possibly the length of residence in the area affected by the sanctuary.

Applicants who are chosen as members should expect to serve three-year terms, pursuant to the council's Charter.

DATES: Applications are due by August 2, 2010.

ADDRESSES: Application kits may be obtained from Jennifer Morgan, NOAA—Flower Garden Banks National Marine Sanctuary, 4700 Avenue U, Bldg. 216, Galveston, TX 77551 or downloaded from the sanctuary Web site *http://flowergarden.noaa.gov.* Completed applications should be sent to the same address.

FOR FURTHER INFORMATION CONTACT: Jennifer Morgan, NOAA—Flower Garden Banks National Marine Sanctuary, 4700 Avenue U, Bldg. 216, Galveston, TX 77551, 409–621–5151 ext. 103, *Jennifer.Morgan@noaa.gov.*

SUPPLEMENTARY INFORMATION: Located in the northwestern Gulf of Mexico, the Flower Garden Banks National Marine Sanctuary includes three separate areas, known as East Flower Garden, West Flower Garden, and Stetson Banks. The Sanctuary was designated on January 17, 1992. Stetson Bank was added to the Sanctuary in 1996. The Sanctuary Advisory Council will consist of no more than 21 members; 16 non-governmental voting members and 5 governmental non-voting members. The Council may serve as a forum for consultation and deliberation among its members and as a source of advice to the Sanctuary manager regarding the management of the Flower Garden Banks National Marine Sanctuary.

Authority: 16 U.S.C. 1431, *et seq.*

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: June 14, 2010.

Daniel J. Basta,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2010–15095 Filed 6–23–10; 8:45 am]

BILLING CODE 3510–22–M

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–C–2010–0053]

Notice of Enforcement Policy Symposium on Combating Counterfeiting in the 21st Century

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of public symposium.

SUMMARY: To focus on the United States Government enforcement policy regarding counterfeit goods involving health and safety concerns and the United States Patent and Trademark Office's (USPTO) efforts at home and abroad combating counterfeiting, the USPTO and the National Intellectual Property Rights Coordination Center (IPR Center) are co-hosting an enforcement policy symposium on combating counterfeiting in the 21st century. A three panel program is planned for the symposium addressing counterfeiting through regulatory procedures, criminal procedures, and training/public awareness. There are a limited number of seats allocated for members of the public who wish to attend and observe the symposium. Requests to attend the symposium are required and must be submitted by electronic mail through the Internet to: *elizabeth.shaw2@uspto.gov.* Requests to attend the symposium should indicate the following information: (1) The name of the person desiring to attend; (2) the person's contact information (telephone number and electronic mail address); and (3) the organization(s) the person represents, if any.

Dates and Times: The symposium will be held on Wednesday, July 14, 2010, from 1 p.m. to 4 p.m. The deadline for receipt of requests to observe the symposium is 5 p.m. on Wednesday, July 7, 2010.

ADDRESSES: The symposium will be held at the USPTO, Madison Auditorium, Concourse Level, 600 Dulany Street, Alexandria, Virginia, 22314.

FOR FURTHER INFORMATION CONTACT: Elizabeth Shaw, Office of External Affairs, by phone 571–272–8494, by facsimile to 571–273–0121, by e-mail at *elizabeth.shaw2@uspto.gov* or by mail addressed to: Mail Stop OIPPE, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, Virginia 22313–1450, ATTN: Elizabeth Shaw.

SUPPLEMENTARY INFORMATION: The Enforcement Policy Symposium on Combating Counterfeiting in the 21st

Century will consist of three panel discussions focused on the challenges and opportunities presented, changes in the intellectual property enforcement landscape, and interagency cooperation. A panel on regulatory authority will address enforcement policy involving counterfeiting and the regulatory response. A second panel on criminal procedure will involve a discussion of enforcement policy involving the investigation and prosecution of counterfeit goods involving health and safety concerns. A third panel on the United States Government's domestic and international training efforts relating to counterfeiting and public awareness is the final panel. Government agencies that provide enforcement training and public awareness programs will be featured.

Should there be time during the symposium, questions from members of the public in attendance may be addressed.

The USPTO plans to make the symposium available via Web cast. Web cast information will be available on the USPTO's Internet Web site, *http://www.uspto.gov,* before the symposium.

Dated: June 18, 2010.

David J. Kappos,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2010–15307 Filed 6–23–10; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No.: PTO–P–2010–0048]

Expansion and Extension of the Patent Application Backlog Reduction Stimulus Plan

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO) published a notice in the **Federal Register** providing an additional temporary basis (the Patent Application Backlog Reduction Stimulus Plan) under which a small entity applicant may have an application accorded special status for examination if the applicant expressly abandons another copending unexamined application. The Patent Application Backlog Reduction Stimulus Plan allows small entity applicants having multiple applications currently pending before the USPTO to have greater control over the priority with which their applications are examined while also stimulating a reduction of the backlog of unexamined patent applications pending before the USPTO. The USPTO is expanding the Patent Application Backlog Reduction Stimulus Plan to permit all applicants to participate by eliminating the small entity status requirement and adding a few new requirements in view of the expansion. The program is also being extended until December 31, 2010, or the date that 10,000 applications have been accorded special status for examination under the Patent Application Backlog Reduction Stimulus Plan, whichever occurs earlier. These changes allow more applicants to take advantage of the program.

DATES: *Effective Date:* The changes in this notice are effective on June 24, 2010. The Patent Application Backlog Reduction Stimulus Plan became effective on November 27, 2009.

FOR FURTHER INFORMATION CONTACT: Pinchus M. Laufer, Office of the Associate Commissioner for Patent Examination Policy, by telephone at 571–272–7726; or via e-mail addressed to *Pinchus.Laufer@uspto.gov;* or by mail addressed to: Box Comments Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450.

SUPPLEMENTARY INFORMATION: The USPTO published a notice in the **Federal Register** providing an additional temporary basis (the Patent Application Backlog Reduction Stimulus Plan) under which a small entity applicant may have an application accorded special status for examination if the applicant expressly abandons another copending unexamined application. *See Patent Application Backlog Reduction Stimulus Plan,* 74 FR 62285 (Nov. 27, 2009), 1349 *Off. Gaz. Pat. Off.* 304 (Dec. 22, 2009) (hereinafter "*Backlog Reduction Notice*"). The Patent Application Backlog Reduction Stimulus Plan allows small entity applicants having multiple applications currently pending before the USPTO to have greater control over the priority with which their applications are examined while also stimulating a reduction of the backlog of unexamined patent applications pending before the USPTO. The USPTO indicated that the program would last for a period ending on February 28, 2010, but may be extended for an additional time period thereafter. *See Patent Application Backlog Reduction Stimulus Plan,* 74 FR at 62287, 1349 *Off. Gaz. Pat. Off.* at 306. The USPTO extended the Patent Application Backlog Reduction Stimulus Plan until June 30, 2010. *See Extension of the Patent Application Backlog Reduction Stimulus Plan,* 75 FR 5041 (Feb. 1, 2010), 1351 *Off. Gaz. Pat. Off.* 202 (Feb. 23, 2010). The notice stated that the USPTO may further extend the procedures set forth in this notice to all applicants (on either a temporary or permanent basis), or may also discontinue the procedures set forth in this notice after June 30, 2010, depending upon the results of the Patent Application Backlog Reduction Stimulus Plan.

The *Backlog Reduction Notice* required *inter alia* that the application for which special status is sought is a nonprovisional application that has an actual filing date earlier than October 1, 2009, in which the applicant has established small entity status under 37 CFR 1.27. The program is being expanded to permit all applicants to participate by eliminating the small entity status requirement and adding a few new requirements in view of the expansion. The modifications set forth in this notice will apply to any petitions that are filed on or after the publication date of this notice. This will permit more applications to qualify for the program and result in a greater reduction of the patent application backlog. Applicants may obtain special status for examination for as many as fifteen applications under this program.

Effective immediately, the USPTO will accord special status for examination to a patent application that has an actual filing date earlier than October 1, 2009, if the new requirements set forth in this notice are satisfied, and the conditions set forth in the *Backlog Reduction Notice* published on November 27, 2009, other than the small entity status requirement, are also satisfied. In view of the expansion, the following new requirements are added to the program: (1) The letter of express abandonment filed in the copending nonprovisional application must also include a statement that the applicant has not and will not file a new application that claims the same invention claimed in the expressly abandoned application (the phrase "same invention" has the same meaning as used in the context of statutory double patenting under 35 U.S.C. 101); (2) the applicant has not received special status for more than fourteen other applications under this program; and (3) the petition under 37 CFR 1.102 must also: (i) Include a specific identification of the relationship between the applications that qualifies the application for special status (*e.g.,* identifying, by name, a common inventor, assignee or owner); (ii) identify, by application number if

available, the application that is being expressly abandoned; (iii) provide a statement certifying that applicant has not filed petitions in more than fourteen other applications requesting special status under this program; and (iv) provide a statement that applicant agrees to make an election without traverse in a telephonic interview if the Office determines that the claims of the application to be made special are directed to two or more independent and distinct inventions (*see* 35 U.S.C. 121, 37 CFR 1.141–142). If the examiner cannot reach the applicant after a reasonable effort or applicant refuses to make an election in a telephonic interview, the examiner will treat the first claimed invention as constructively elected without traverse for examination. In addition, the USPTO will accord special status for examination under the Patent Application Backlog Reduction Stimulus Plan to only the first 10,000 applications that meet the requirements of the Patent Application Backlog Reduction Stimulus Plan.

For the purpose of the certification that applicant has not filed petitions in more than fourteen other applications requesting special status under this program, any application that is assigned to or subject to an obligation to assign to an entity or is owned by that entity for which a petition under this program has been filed is considered to be a petition filed by applicant. Thus, the certification that applicant has not filed petitions in more than fourteen other applications requesting special status under this program is based upon ownership.

The procedure specified in the *Backlog Reduction Notice* and this notice is applicable to applicants having multiple applications currently pending before the USPTO and who are willing to expressly abandon one application to have another application accorded special status for examination. The USPTO appreciates that there are applicants who are willing to expressly abandon an application, but who have only a single application pending before the USPTO or no application for which special status for examination is desired. Applicants are reminded that 37 CFR 1.138(d) provides a procedure by which an applicant may obtain a refund of the search fee and excess claims fee paid in an application by submitting a petition (requires no fee) and letter of express abandonment. *See* MPEP § 711. 01. The procedure set forth in 37 CFR 1.138(d), however, is applicable only to applications filed under 35 U.S.C. 111(a) on or after December 8, 2004.

Applicants are cautioned to exercise care in filing a letter of express abandonment in an application. The USPTO cannot revive an application once the letter of express abandonment is recognized by the USPTO because the application was expressly and intentionally abandoned by the applicant. *See* MPEP §§ 711.01 and 711.03(c).

The procedure for petition under 37 CFR 1.102 to make an application special specified in the *Backlog Reduction Notice* and this notice is being adopted on a temporary basis until December 31, 2010. For a petition under 37 CFR 1.102 to be granted under the procedure specified in this notice, the petition under 37 CFR 1.102 and the letter of express abandonment and its accompanying statement must be filed on or before December 31, 2010, and must be among the first 10,000 applications accorded special status for examination under the Patent Application Backlog Reduction Stimulus Plan.

Dated: June 18, 2010.

David J. Kappos,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2010–15306 Filed 6–23–10; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XM26

Marine Mammals; File No. 14186

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permit.

SUMMARY: Notice is hereby given that Sea World LLC, 9205 South Park Center Loop, Suite 400, Orlando, FL 32819 [Brad Andrews, Responsible Party] has been issued an enhancement permit to maintain non-releasable stranded Guadalupe fur seals (*Arctocephalus townsendi*).

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following office(s):

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)713–0376; and

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213; phone (562)980–4001; fax (562)980–4018.

FOR FURTHER INFORMATION CONTACT: Jennifer Skidmore or Amy Sloan, (301)713–2289.

SUPPLEMENTARY INFORMATION: On December 19, 2008, notice was published in the **Federal Register** (73 FR 77630) that a request for a permit to conduct enhancement on the species identified above had been submitted by the above-named applicant. The requested permit has been issued under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226). Additional authorization is provided pursuant to sections 109(h) and 112(c) of the Marine Mammal Protection Act of 1972 as amended (MMPA; 16 U.S.C. 1361 *et seq.*).

Permit No. 14186 authorizes Sea World LLC to maintain up to six (6) non-releasable stranded Guadalupe fur seals over a five-year period.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Issuance of this permit, as required by the ESA, was based on a finding that such permit: (1) was applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: June 18, 2010.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2010–15322 Filed 6–23–10; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Stellwagen Bank National Marine Sanctuary Final Revised Management Plan: Notice of Availability

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of availability.

SUMMARY: The final revised management plan for the Stellwagen Bank National Marine Sanctuary (SBNMS) has been approved and is now available. This plan is the result of a multi-year review at the SBNMS and ONMS, and included extensive public, as well as state, local and other Federal agency involvement. The plan is available for download on the Web site: *http://stellwagen.noaa.gov.* For a hard copy or data CD of the plan contact the sanctuary office at the contact number identified below.

DATES: The final revised management plan is available to the public on June 17, 2010.

FOR FURTHER INFORMATION CONTACT: Anne Smrcina, Stellwagen Bank National Marine Sanctuary, 175 Edward Foster Road, Scituate, MA 02066; 781–545–8026; *anne.smrcinanoaa.gov.*

Dated: June 14, 2010.

Daniel J. Basta,

Director, Office of National Marine Sanctuaries.

[FR Doc. 2010–15097 Filed 6–23–10; 8:45 am]

BILLING CODE 3510–22–M

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act; Notice of Meeting

TIME AND DATE: Wednesday, June 30, 2010; 11 a.m.–12 Noon.

PLACE: Hearing Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, Maryland.

STATUS: Closed to the public.

MATTERS TO BE CONSIDERED:

Compliance Status Report

The Commission staff will brief the Commission on the status of compliance matters.

For a recorded message containing the latest agenda information, call (301) 504–7948.

CONTACT PERSON FOR MORE INFORMATION: Todd A. Stevenson, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7923.

Dated: June 21, 2010.

Todd A. Stevenson,

Secretary.

[FR Doc. 2010–15512 Filed 6–22–10; 4:15 pm]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Department of the Navy

Meeting of the Ocean Research and Resources Advisory Panel

AGENCY: Department of the Navy, DoD.

ACTION: Notice of Open Meeting.

SUMMARY: The Ocean Research and Resources Advisory Panel (ORRAP) will hold a regularly scheduled meeting. The meeting will be open to the public.

DATES: The meeting will be held on Tuesday, July 27, 2010, from 8:30 a.m. to 5:30 p.m. and on Wednesday, July 28, 2010, from 8:30 a.m. to 2 p.m. Members of the public should submit their comments in advance of the meeting to the meeting Point of Contact.

ADDRESSES: The meeting will be held at the Alaska SeaLife Center, 301 Railway Ave., Seward, AK 99664.

FOR FURTHER INFORMATION CONTACT: Dr. Charles L. Vincent, Office of Naval Research, 875 North Randolph Street, Suite 1425, Arlington, VA 22203–1995, telephone 703–696–4118.

SUPPLEMENTARY INFORMATION: This notice of open meeting is provided in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2). The meeting will include discussions on ocean research, resource management, and other current issues in the ocean science and management communities.

Dated: June 17, 2010.

H.E. Higgins,

Lieutenant, Judge Advocate Generals Corps, U.S. Navy, Alternate Federal Register Liaison Officer.

[FR Doc. 2010–15294 Filed 6–23–10; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Acting Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before August 23, 2010.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.* new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: June 21, 2010.

James Hyler,

Acting Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management.

Federal Student Aid

Type of Review: New.

OMB Number: Pending.

Title: Student Assistance General Provisions—Satisfactory Academic Progress Policy.

Frequency: On Occasion.

Affected Public: Individuals or household; Not-for-profit institutions; State, Local, or Tribal Gov't, State Educational Agencies (SEAs) or Local Educational Agencies (LEAs).

Reporting and Recordkeeping Hour Burden:

Responses: 21,672,244.

Burden Hours: 977,033.

Abstract: These regulations identify the policies and procedures to ensure

that students are making satisfactory academic progress in their program at a pace and a level to receive or continue to receive Title IV Higher Education Act of 1965, as amended (HEA) program funds.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the "Browse Pending Collections" link and by clicking on link number 4267. When you access the information collection, click on "Download Attachments" to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 2010–15341 Filed 6–23–10; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA Number 84.215P]

Promise Neighborhoods Program

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Notice inviting applications for new awards for fiscal year (FY) 2010; correction; extension of application deadline.

SUMMARY: On May 5, 2010, we published in the **Federal Register** (75 FR 10492) a notice inviting applications for new awards for FY 2010 for the Promise Neighborhoods Program (May 5 notice). The May 5 notice established a deadline of June 25, 2010, for the submission of applications under this competition. Through this notice, we are correcting the May 5 notice and are extending the deadline for transmittal of applications and the deadline for intergovernmental review.

SUPPLEMENTARY INFORMATION:

Correction. This notice corrects the May 5 notice by removing language that established a maximum page limit for the application narrative for applications submitted under this competition. We are taking this action because the maximum page limit established for the application narrative was an administrative error and unduly restricts applicant flexibility. To correct this error, the Department makes the following correction to the May 5 notice:

On page 24680, second column, the last paragraph, the word "must" is replaced with the words "are strongly encouraged to".

Extension. In light of this error, we are extending the deadline for the transmittal of applications to June 28, 2010, and the deadline for intergovernmental review to August 27, 2010. The updated dates are as follows:

Deadline for Transmittal of Applications: June 28, 2010.

Deadline for Intergovernmental Review: August 27, 2010.

FOR FURTHER INFORMATION CONTACT: Larkin Tackett, U.S. Department of Education, 400 Maryland Avenue, SW., Room 4W338, Washington, DC 20202–5970. *Telephone:* (202) 453–6615 or by e-mail: *promiseneighborhoods@ed.gov.*

If you use a telecommunications device for the deaf, call the Federal Relay Service, toll free, at 1–800–877–8339.

Electronic Access to This Document: You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.* To use PDF you must have Adobe Acrobat Reader, which is available free at this site.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: June 21, 2010.

James H. Shelton, III,

Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2010–15346 Filed 6–23–10; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

Sunshine Act Notice

AGENCY: U.S. Election Assistance Commission.

ACTION: Notice of Public Meeting and Hearing Agenda.

DATE & TIME: Monday, June 28, 2010, 10 a.m.—12 p.m. CDT (Morning Session), 1–4 p.m. CDT (Afternoon Session).

PLACE: Sheraton Chicago Hotel and Towers, 301 East North Water Street, Chicago, IL 60611, (312) 464–1000.

MEETING AGENDA: The Commission will hold a public meeting to hold a discussion on a clearinghouse policy. Commissioners will act on the following matters: (1) Consider and vote on a Maintenance of Expenditure (MOE) policy; (2) consider and vote on the publication of proposed draft National Voter Registration Act (NVRA) regulations for public comment. Commissioners will consider other administrative matters.

HEARING AGENDA: The Commission will conduct a public hearing to receive presentations on the following topic: Voting System Pre-Election Logic and Accuracy Testing and Post-Election Audit Grants. Members of the public who wish to speak at the hearing, regarding voting system pre-election logic and accuracy testing and post-election audit grants may send a request to participate to the EAC by 12 Noon CDT June 28, 2010. Due to time constraints, the EAC can select no more than ten participants amongst the volunteers who request to participate. The selected volunteers will be allotted three-minutes each to share their viewpoint. Participants will be selected on a first-come, first-served basis. However, to maximize diversity of input, only one participant per organization or entity will be chosen if necessary. Participants may also submit written testimony to be published at *http://www.eac.gov.* Requests to speak may be sent to the EAC via e-mail at *testimony@eac.gov,* via mail addressed to the U.S. Election Assistance Commission, 1201 New York Avenue, NW., Suite 300, Washington, DC 20005, or by fax at 202–566–1392. All requests must include a description of what will be said, contact information which will be used to notify the requestor with status of request (phone number on which a message may be left or e-mail), and include the subject/attention line (or on the envelope if by mail): Grants: Logic/Accuracy/Audits. Please note that these comments will be made available to the public at *http://www.eac.gov.*

Written comments from members of the public, regarding voting system pre-election logic and accuracy testing and post-election audit grants will also be accepted. This testimony will be included as part of the written record of the hearing, and available on our Web site. Written testimony must be received by 5 pm. CDT June 28, 2010, and should be submitted via e-mail at *testimony@eac.gov,* via mail addressed to the U.S. Election Assistance

Commission, 1201 New York Avenue, NW., Suite 300, Washington, DC 20005, or by fax at 202–566–1392. All correspondence that contains written testimony must have in the subject/attention line (or on the envelope if by mail): Written Submission for Grants: Logic/Accuracy/Audits.

Members of the public may observe but not participate in EAC meetings unless this notice provides otherwise. Members of the public may use small electronic audio recording devices to record the proceedings. The use of other recording equipment and cameras requires advance notice to and coordination with the Commission's Communications Office.*

* View *EAC Regulations Implementing Government in the Sunshine Act.*

This Meeting and Hearing Will Be Open to the Public.

PERSON TO CONTACT FOR INFORMATION: Bryan Whitener, Telephone: (202) 566–3100.

Signed:

Donetta Davidson,

Chair, U.S. Election Assistance Commission.

[FR Doc. 2010–15535 Filed 6–22–10; 4:15 pm]

BILLING CODE 6820–KF–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2010–0488 FRL–8830–2]

Agency Information Collection Activities; Proposed Collection; Comment Request; Chemical-Specific Rules, TSCA Section 8(a); EPA ICR No. 1198.09, OMB Control No. 2070–0067

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a request to renew an existing approved Information Collection Request (ICR) to the Office of Management and Budget (OMB). This ICR, entitled: "Chemical-Specific Rules, TSCA Section 8(a)" and identified by EPA ICR No. 1198.09 and OMB Control No. 2070–0067, is scheduled to expire on January 31, 2011. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection.

DATES: Comments must be received on or before August 23, 2010.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2010–0488 by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery*: OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2010–0488. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2010–0488. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov*, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Karen Chu, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8773; fax number: (202) 564–9490; e-mail address: *chu.karen@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. What Information is EPA Particularly Interested In?

Pursuant to section 3506(c)(2)(A) of PRA, EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Enhance the quality, utility, and clarity of the information to be collected.

4. Minimize the burden of the collection of information on those who are to respond, including through the

use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What Should I Consider when I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the collection activity.
7. Make sure to submit your comments by the deadline identified under **DATES**.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

III. What Information Collection Activity or ICR Does this Action Apply to?

Affected entities: Entities potentially affected by this ICR are those businesses that fall under the North American Industrial Classification System (NAICS) codes 325, chemical manufacturers and processors, and 324110, petroleum refineries.

Title: Chemical-Specific Rules, TSCA Section 8(a).

ICR numbers: EPA ICR No. 1198.09, OMB Control No. 2070–0067.

ICR status: This ICR is currently scheduled to expire on January 31, 2011. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: The Toxic Substances Control Act (TSCA) section 8(a) authorizes the Administrator of EPA to promulgate rules that require persons who manufacture, import, or process chemical substances and mixtures, or who propose to manufacture, import, or process chemical substances and mixtures, to maintain such records and submit such reports to EPA as may be reasonably required. Any chemical covered by TSCA for which EPA or another Federal agency has a reasonable need for information and which cannot be satisfied via other sources is a proper potential subject for a chemical-specific TSCA section 8(a) rulemaking. Information that may be collected under TSCA section 8(a) includes, but is not limited to, chemical names, categories of use, production volume, byproducts of chemical production, existing data on deaths and environmental effects, exposure data, and disposal information. Generally, EPA uses chemical-specific information under TSCA section 8(a) to evaluate the potential for adverse human health and environmental effects caused by the manufacture, importation, processing, use or disposal of identified chemical substances and mixtures. Additionally, EPA may use TSCA section 8(a) information to assess the need or set priorities for testing and/or further regulatory action. To the extent that reported information is not considered confidential, environmental groups, environmental justice advocates, state and local government entities and other members of the public will also have access to this information for their own use.

Responses to the collection of information are mandatory (see 40 CFR part 704). Respondents may claim all or part of a notice confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 68.8 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The ICR provides a detailed explanation of this estimate, which is only briefly summarized here:

Estimated total number of potential respondents: 4.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 1.

Estimated total annual burden hours: 275 hours.

Estimated total annual costs: $14,080. This includes an estimated burden cost of $14,080 and an estimated cost of $0 for capital investment or maintenance and operational costs.

IV. Are There Changes in the Estimates from the Last Approval?

There is no change in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB.

V. What is the Next Step in the Process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects

Environmental protection, Reporting and recordkeeping requirements.

Dated: June 17, 2010.

Stephen A. Owens,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2010–15330 Filed 6–23–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9167–5]

Clean Air Act Operating Permit Program; Petition for Objection to a Federal Operating Permit for Waste Management of Louisiana L.L.C., Woodside Landfill and Recycling Center (WLRC), Walker, Livingston Parish, LA

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final action.

SUMMARY: This document announces that the EPA Administrator has responded to a citizen petition asking EPA to object to the part 70 Operating Permit for WLRC, Walker, Livingston Parish, Louisiana, issued by the Louisiana Department of Environmental Quality. Specifically, the Administrator has partially granted and partially denied the petition submitted by Tulane Environmental Law Clinic on behalf of the Louisiana Environmental Action Network, Concerned Citizens of Livingston Parish, Mr. O'Neil Couvillion, and Mr. Harold Wayne Breaud (Petitioners), to object to the part 70 operating permit for WLRC in Livingston Parish, Louisiana

Pursuant to section 505(b)(2) of the Clean Air Act (Act), the petitioner may seek judicial review of those portions of the petition which EPA denied in the United States Court of Appeals for the appropriate circuit. Any petition for review shall be filed within 60 days from the date this notice appears in the **Federal Register**, pursuant to section 307 of the Act.

ADDRESSES: You may review copies of the final order, the petition, and other supporting information at EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view copies of the final order, petition, and other supporting information. If you wish to examine these documents, you should make an appointment at least 24 hours before visiting day. The final order is also available electronically at: *http://www.epa.gov/region07/air/title5/petitiondb/petitions/woodside_decision2009.pdf.*

FOR FURTHER INFORMATION CONTACT: Bonnie Braganza, Air Permits Section, Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, telephone (214) 665–7340, or email at *braganza.bonnie@epa.gov.*

SUPPLEMENTARY INFORMATION: The Act affords EPA a 45-day period to review, and, as appropriate, object to operating permits proposed by State permitting authorities under Title V of the Act. Section 505(b)(2) of the Act authorizes any person to petition the EPA Administrator within 60 days after the expiration of this review period to object to title V operating permits if EPA has not done so. Petitions must be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided by the State, unless the petitioner demonstrates that it was impracticable to raise these issues during the comment period or the grounds for the issues arose after this period.

On January 2, 2009, EPA received a petition from the Petitioners requesting that EPA object to the issuance of the title V operating permit to WLRC for the operation of the landfill in Walker, Livingston Parish, Louisiana. The petitioners claim that: (1) The title V permit fails to include monitoring requirements sufficient to assure compliance with permit limits; (2) LDEQ erred in determining the amount of carbon monoxide emissions for purposes of assessing the applicability of Prevention of Significant Deterioration requirements; (3) the title V permit fails to include nonattainment new source review; and (4) LDEQ failed to meet the public notice requirements before issuing the title V permit.

On May 27, 2010, the Administrator issued an order partially granting and partially denying the petition. The order explains the reasons behind EPA's conclusion to partially grant and partially deny the petition for objection.

Dated: June 11, 2010.

Al Armendariz,

Regional Administrator, Region 6.

[FR Doc. 2010–15331 Filed 6–23–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9167–9]

Notice of a Regional Project Waiver of Section 1605 (Buy American) of the American Recovery and Reinvestment Act of 2009 (ARRA) to the City of Newport, RI

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA is hereby granting a waiver of the Buy American requirements of ARRA Section 1605 under the authority of Section 1605(b)(2) [manufactured goods are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality] to the City of Newport, RI ("City") for the purchase of a foreign manufactured ultraviolet (UV) light disinfection treatment system for the Easton Beach Project in Newport, Rhode Island. This is a project specific waiver and only applies to the use of the specified product for the ARRA project being proposed. Any other ARRA recipient that wishes to use the same product must apply for a separate waiver based on project specific circumstances. Based upon information submitted by the City and its consulting engineer, it has been determined that there are currently no domestically manufactured UV disinfection treatment systems available to meet the City's project specifications and construction schedule. The Regional Administrator is making this determination based on the review and recommendations of the Municipal Assistance Unit. The Assistant Administrator of the Office of Administration and Resources Management has concurred on this decision to make an exception to Section 1605 of ARRA. This action permits the purchase of a foreign manufactured UV light disinfection treatment system by the City, as specified in its February 4, 2010 request.

DATES: *Effective Date:* June 15, 2010.

FOR FURTHER INFORMATION CONTACT: Katie Connors, Environmental Engineer, (617) 918–1658, or David Chin, Environmental Engineer, (617) 918–1764, Municipal Assistance Unit (CMU), Office of Ecosystem Protection (OEP), U.S. EPA, 5 Post Office Square, Suite 100, Boston, MA 02109–3912.

SUPPLEMENTARY INFORMATION: In accordance with ARRA Section 1605(c), the EPA hereby provides notice that it is granting a project waiver of the requirements of Section 1605(b)(2) of Public Law 111–5, Buy American requirements, to the City of Newport, RI ("City") for the purchase of a non-domestically manufactured medium-pressure UV light disinfection treatment system from Trojan Technologies, manufactured in Canada, to meet the City's design and performance specifications and construction schedule as part of its proposed Easton Beach Project in Newport, RI. Trojan Technologies has a U.S. manufacturing facility in Ontario, California, but that site is not currently equipped to conduct a specific product test

procedure required for this project's specifications.

Section 1605 of the ARRA requires that none of the appropriated funds may be used for the construction, alteration, maintenance, or repair of a public building or a public works project unless all of the iron, steel, and manufactured goods used in the project is produced in the United States, or unless a waiver is provided to the recipient by the head of the appropriate agency, here the EPA. A waiver may be provided if EPA determines that (1) Applying these requirements would be inconsistent with the public interest; (2) iron, steel, and the relevant manufactured goods are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality; or (3) inclusion of iron, steel, and the relevant manufactured goods produced in the United States will increase the cost of the overall project by more than 25 percent.

The City is proposing a disinfection system to treat storm water discharging into Easton Beach, a recreational area. The UV disinfection system is designed to treat as much as 62 MGD of storm water that has historically been the source of elevated concentration levels of bacterial contamination sufficient to cause health officials to close the Easton Beach area for recreational purposes during certain weather/runoff events.

The project specifications are for a medium pressure UV light disinfection system capable of treating up to 62 MGD with the following parameters: (1) Minimum 55% UV transmittance in storm water runoff, with a minimum of 30 mg/L total suspended solids (TSS) concentration, (2) 40 mW-sec/cm^2 applied UV dose, (3) The Rhode Island Department of Health beach closure standard is that each sample shall be less than or equal to 104 *Enterococci* colonies/100 mL; a 20 year lifetime process performance guarantee will be required of the disinfection system supplier, (4) Allowable headloss at Peak Flow 18 inches, maximum from the controlling weir to the discharge pumps outlet, (5) Requisite UV dose at 254 nm wavelength: 40 mW-sec/cm^2, (6) Ultraviolet transmittance at 253.7 nm: 55%, and (7) effluent to be able to meet 30 mg/L of Total Suspended Solids (TSS).

Trojan Technologies ("Trojan") manufactures the applicable 3000+ UV disinfection treatment unit domestically in the Ontario, California plant as well as outside the U.S. in Canada. However, due to the beach closure standard by the RIDOH and the specification of a 20 year lifetime process performance guarantee for the UV system, the product will be subject to a device test cell procedure. Trojan's California site is not equipped for this test procedure at this time. However, the Canadian site is currently equipped for the test. The test is performed at the site of manufacture in Canada, according to the City's design engineer.

The supporting documentation and independent research and communication with select manufacturers of medium pressure UV disinfection systems conducted by EPA's national contractor demonstrate that there are no U.S. manufacturers able to meet all the project specifications and the construction schedule. The design engineer for the City had identified one domestic manufacturer in the United States. According to the City's design engineer, although the domestic manufacturer could meet most of the project specifications and performance criteria, if the City used the domestic UV disinfection system, a redesign of the system would be required before construction could take place. The domestic system is larger than the proposed Trojan system and an increase in the size of the structure housing for the UV system would be necessary. Additionally, the electrical system of the UV system would also need to be redesigned if the domestic system was used. Project permits that have been approved for the proposed Trojan system would likely have to be modified and/or new permits would need to be secured because of the increase in the size of the structure. EPA confirmed that the footprint would increase by 50 percent for the domestic system. There has already been considerable public concern regarding the size of the actual proposed stormwater disinfection structure being located in a popular and busy recreational section of Newport. There is a great deal of local and tourist traffic in the area. In addition, there are a number of site constraints involved with the proposed project. For example, one of the design requirements noted by the City of Newport was that the amount of land that may be disturbed is less than 25,000 square feet in order to minimize impacts to existing buried utilities, the existing street or right-of-way, as well as the nearby stream and dam. The City is concerned that significantly increasing the size of the structure will raise additional public concern and would indefinitely delay the project. The redesign of the structure would take months to complete and that along with the expected permitting process would ultimately delay the construction of the project by at least 2–3 months. An independent review of the submitted documentation by EPA's national contractor confirmed this evidence.

Furthermore, the purpose of the ARRA is to stimulate economic recovery by funding current infrastructure construction, not to delay projects that are "shovel ready" by requiring potential SRF eligible recipients, such as the City of Newport, RI, to revise their design standards and specifications as well as their construction schedule. The imposition of ARRA Buy American requirements in this case would result in unreasonable delay for this project. To delay this construction would directly conflict with a fundamental economic purpose of ARRA, which is to create or retain jobs. In addition, the timely construction of the new stormwater disinfection system would allow further protection of Easton Beach and its users. The project delays are of particular concern for implementation of the system within the recreation season of 2010.

The April 28, 2009 EPA HQ Memorandum, "Implementation of Buy American provisions of P.L. 111–5, the 'American Recovery and Reinvestment Act of 2009' " ("Memorandum"), defines *reasonably available quantity* as "the quantity of iron, steel, or relevant manufactured good is available or will be available at the time needed and place needed, and in the proper form or specification as specified in the project plans and design." The same Memorandum defines "satisfactory quality" as "the quality of steel, iron or manufactured good specified in the project plans and designs."

The Municipal Assistance Unit (CMU) has reviewed this waiver request and has determined that the supporting documentation provided by the City establishes both a proper basis to specify a particular manufactured good, and that the domestic manufactured good that is currently available does not meet all of the design specifications and the construction schedule for the proposed project. The information provided is sufficient to meet the following criteria listed under Section 1605(b) of the ARRA and in the April 28, 2009 Memorandum: Iron, steel, and the manufactured goods are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality.

The March 31, 2009 Delegation of Authority Memorandum provided Regional Administrators with the temporary authority to issue exceptions to Section 1605 of the ARRA within the geographic boundaries of their

respective regions and with respect to requests by individual grant recipients.

Having established both a proper basis to specify the particular good required for this project and that this manufactured good was not available from a producer in the United States, the City is hereby granted a waiver from the Buy American requirements of Section 1605(a) of Public Law 111–5. This waiver permits use of ARRA funds for the purchase of a non-domestic manufactured ultraviolet light disinfection treatment system documented in City's waiver request submittal dated February 4, 2010. This supplementary information constitutes the detailed written justification required by Section 1605(c) for waivers based on a finding under subsection (b).

Authority: Pub. L. 111–5, section 1605.

Dated June 15, 2010.

Ira W. Leighton,

Acting Regional Administrator, EPA Region 1—New England.

[FR Doc. 2010–15342 Filed 6–23–10; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[GN Docket No. 10–127; FCC 10–114]

Framework for Broadband Internet Service

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document begins an open, public process to consider the adequacy of the current legal framework within which the Commission promotes investment and innovation in, and protects consumers of, broadband Internet service. Recent developments—including a decision of the United States Court of Appeals for the District of Columbia Circuit and affirmation from Congress that the Commission plays a vital role with respect to broadband—lead the Commission to seek comment on our legal framework for broadband Internet service.

DATES: Comments must be submitted by July 15, 2010, and reply comments must be submitted by August 12, 2010.

ADDRESSES: You may submit comments, identified by GN Docket No. 10–127, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web Site: http://fjallfoss.fcc.gov/ecfs2/.* Follow the instructions for submitting comments.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Chris Killion or David Tannenbaum, Office of General Counsel, 202–418–1700.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Inquiry (Notice), FCC 10–114, adopted on June 17, 2010, and released on June 17, 2010. Interested parties may file comments on or before July 15, 2010, and reply comments on or before August 12, 2010. Comments and reply comments may be filed: (1) Using the Commission's Electronic Comment Filing System (ECFS), (2) using the Federal Government's eRulemaking Portal, or (3) by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121, May 1, 1998. All filings related to this Notice should refer to GN Docket No. 10–127. Further, we strongly encourage parties to develop responses to this Notice that adhere to the organization and structure of this Notice.

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://fjallfoss.fcc.gov/ecfs2/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St., SW., Room TW–A325, Washington, DC 20554. The filing hours are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of *before* entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street, SW., Washington, DC 20554.

Parties shall also serve one copy with the Commission's copy contractor, Best Copy and Printing, Inc. (BCPI), Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, (202) 488–5300, or via e-mail to *fcc@bcpiweb.com.*

The inquiry this Notice initiates shall be treated as a "permit-but-disclose" proceeding in accordance with the Commission's ex parte rules. Persons making oral ex parte presentations are reminded that memoranda summarizing the presentations must contain summaries of the substance of the presentations and not merely a listing of the subjects discussed. More than a one or two sentence description of the views and arguments presented generally is required. Other requirements pertaining to oral and written presentations are set forth in section 1.1206(b) of the Commission's rules. Ex parte comments may be filed at any time except during the Sunshine Period. Ex parte comments may be filed: (1) Using the Commission's Electronic Comment Filing System (ECFS), (2) using the Federal Government's eRulemaking Portal, (3) by filing paper copies, or (4) by posting comments and ideas on the Broadband.gov blog at *http://blog.broadband.gov/?categoryId=494971* or on *http://broadband.ideascale.com/a/ideafactory.do?discussionID=11271.* In addition to the usual methods for filing ex parte comments, the Commission is allowing ex parte comments in this proceeding to be filed by posting comments on *http://blog.broadband.gov/?categoryId=494971* and on *http://broadband.ideascale.com/a/ideafactory.do?discussionID=11271.* Accordingly, persons wishing to examine the record in this proceeding should examine the record on ECFS, *http://blog.broadband.gov/?categoryId=494971* and *http://broadband.ideascale.com/a/ideafactory.do?discussionID=11271.* Although those posting comments on the blog may choose to provide identifying information or may comment anonymously, anonymous comments will not be part of the record in this proceeding and accordingly will not be relied on by the Commission in reaching its conclusions in this rulemaking. The Commission will not rely on anonymous postings in reaching conclusions in this matter because of

the difficulty in verifying the accuracy of information in anonymous postings. Should posters provide identifying information, they should be aware that although such information will not be posted on the blog, it will be publicly available for inspection upon request.

Documents in GN Docket No. 10–127 will be available for public inspection and copying during business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. The documents may also be purchased from BCPI, telephone (202) 488–5300, facsimile (202) 488–5563, TTY (202) 488–5562, e-mail *fcc@bcpiweb.com.*

People with Disabilities: To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e-mail to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

1. This Notice begins an open, public process to consider the adequacy of the current legal framework within which the Commission promotes investment and innovation in, and protects consumers of, broadband Internet service. In this Notice we use the term "broadband Internet service" to refer to the bundle of services that facilities-based providers sell to end users in the retail market. This bundle allows end users to connect to the Internet, and often includes other services such as e-mail and online storage. In prior orders we have referred to this bundle as "broadband Internet access service." We use the term "wired," as in "wired broadband Internet service," to distinguish platforms such as digital subscriber line (DSL), fiber, cable modem, and broadband over power lines (BPL), from platforms that rely on wireless connections to provide Internet connectivity and other services in the last mile. We refer to the service that may constitute a telecommunications service as "Internet connectivity service" or "broadband Internet connectivity service." As discussed below, Internet connectivity service allows users to communicate with others who have Internet connections, send and receive content, and run applications online. For administrative simplicity we incorporate the same distinction between broadband and narrowband that the Commission applied in the classification orders we revisit here. That is, services with over 200 kbps capability in at least one direction will be considered "broadband" for the particular purposes of these Notices. Until a recent decision of the United States Court of Appeals for the District of Columbia Circuit, there was a settled approach to facilities-based broadband Internet service, which combined minimal regulation with meaningful Commission oversight. The *Comcast* opinion, however, held that the Commission went too far when it relied on its "ancillary authority" to enjoin a cable operator from secretly degrading its customers' lawful Internet traffic. *Comcast* appears to undermine prior understandings about the Commission's ability under the current framework to provide consumers basic protections when they use today's broadband Internet services. Moreover, the current legal classification of broadband Internet service is based on a record that was gathered a decade ago. Congress, meanwhile, has reaffirmed the Commission's vital role with respect to broadband, and the Commission has developed a National Broadband Plan recommending specific agency actions to encourage deployment and adoption. The Plan contains dozens of recommendations to fulfill the congressional aims articulated in the Recovery Act, including specific proposals to increase access and affordability; maximize utilization of broadband Internet services; and enhance public safety, consumer welfare and education throughout the United States. Roughly half of the Plan's recommendations are directed to the Commission itself.

2. These developments lead us to seek comment on our legal framework for broadband Internet service. In addition to seeking original suggestions from commenters, we ask questions about three specific approaches. First addressing the wired service offered by telephone and cable companies and other providers, we seek comment on whether our "information service" classification of broadband Internet service remains adequate to support effective performance of the Commission's responsibilities. We then ask for comment on the legal and practical consequences of classifying Internet connectivity service as a "telecommunications service" to which all the requirements of Title II of the Communications Act would apply. Finally, we identify and invite comment on a third way under which the Commission would: (i) Reaffirm that Internet information services should remain generally unregulated; (ii) identify the Internet connectivity service that is offered as part of wired broadband Internet service (and only this connectivity service) as a telecommunications service; and (iii) forbear under section 10 of the Communications Act from applying all provisions of Title II other than the small number that are needed to implement the fundamental universal service, competition and small business opportunity, and consumer protection policies that have received broad support. We seek comment on the same issues as they relate to terrestrial wireless and satellite broadband Internet services, as well as on other factual and legal issues specific to these wireless services that bear on their appropriate classification. We further seek comment on discrete issues, including the states' proper role with respect to broadband Internet service.

Introduction

3. This Commission exists "[f]or the purpose of regulating interstate and foreign commerce in communication by wire and radio so as to make available, so far as possible, to all people of the United States * * * a rapid, efficient, Nation-wide, and world-wide wire and radio communication service with adequate facilities at reasonable charges, for the purpose of the national defense, [and] for the purpose of promoting safety of life and property through the use of wire and radio communications." During more than 75 years of technological progress—from the time of tube radios and telephone switchboards to the modern era of converged digital services—the Commission has promoted innovation and investment in new communications services and protected and empowered the businesses and consumers who depend on them.

4. We have held to our pro-competition and pro-consumer mission in the Internet Age. Indeed, for at least the last decade the Commission has taken a consistent approach to Internet services—one that industry has endorsed and Congress and the United States Supreme Court have approved. This approach consists of three elements: The Commission generally does not regulate Internet content and applications; access to an Internet service provider via a dial-up connection is subject to the regulatory rules for telephone service; and for the broadband Internet services that most consumers now use to reach the Internet, the Commission has refrained from regulation when possible, but has the authority to step in when necessary to protect consumers and fair competition.

5. The first element of our consistent approach, preserving the Internet's capacity to enable a free and open forum for innovation, speech, education, and job creation, finds expression in (among other provisions) section 230 of the

Communications Act, which states Congress's conclusion that "[t]he Internet and other interactive computer services have flourished, to the benefit of all Americans, with a minimum of government regulation."

6. The second element, oversight of dial-up access to the Internet under the common carriage framework of Title II of the Communications Act, is a facet of traditional telephone regulation. Although Internet users increasingly depend on broadband communications connections for Internet access, approximately 5.6 million American households still use a dial-up telephone connection.

7. The third element of the framework, restrained oversight of broadband Internet service, was expressed clearly on September 23, 2005, for example, when the Commission released two companion decisions. The first "establishe[d] a minimal regulatory environment for wireline broadband Internet access services." It reclassified telephone companies' broadband Internet service offerings as indivisible "information services" subject only to potential regulation under Title I of the Communications Act and the doctrine of ancillary authority. In that decision, the Commission articulated its belief that "the predicates for ancillary jurisdiction are likely satisfied for any consumer protection, network reliability, or national security obligation that we may subsequently decide to impose on wireline broadband Internet access service providers." The second decision that day adopted principles for an open Internet, again expressing confidence that the Commission had the "jurisdiction necessary to ensure that providers of telecommunications for Internet access * * * are operated in a neutral manner." Earlier this year, the Commission unanimously reaffirmed in a *Joint Statement on Broadband* that "[e]very American should have a meaningful opportunity to benefit from the broadband communications era," and that "[w]orking to make sure that America has world-leading high-speed broadband networks—both wired and wireless—lies at the very core of the FCC's mission in the 21st Century." Together, these and other agency decisions show the Commission's commitment to restrained oversight of broadband Internet service, and its equally strong resolve to ensure universal service and protect consumers and fair competition in this area when necessary.

8. Before the *Comcast* case, most stakeholders—including major communications service providers—shared the Commission's view that the information service classification allowed the Commission to exercise jurisdiction over broadband Internet services when required. But the D.C. Circuit concluded that the Commission lacked authority to prohibit practices of a major cable modem Internet service provider that involved secret interruption of lawful Internet transmissions, which the Commission found were unjustified and discriminatory and denied users the ability to access the Internet content and applications of their choice. Today, in the wake of the *Comcast* decision, the Commission faces serious questions about the legal framework that will best enable it to carry out, with respect to broadband Internet service, the purposes for which Congress established the agency. Meanwhile, Congress has highlighted the importance of broadband networks and Internet-based content and services for economic growth and development and has directed the Commission to develop policies to address concerns about the pace of deployment, adoption, and utilization of broadband Internet services in the United States.

9. *Comcast* makes unavoidable the question whether the Commission's current legal approach is adequate to implement Congress's directives. In this Notice, we seek comment on the best way for the Commission to fulfill its statutory mission with respect to broadband Internet service in light of the legal and factual circumstances that exist today. We do so while standing ready to serve as a resource to Congress as it considers additional legislation in this area. Commenters may wish to address how the Commission should proceed on these issues in light of Congressional developments.

10. We emphasize that the purpose of this proceeding is to ensure that the Commission can act within the scope of its delegated authority to implement Congress's directives with regard to the broadband communications networks used for Internet access. These networks are within the Commission's subject-matter jurisdiction over communication by wire and radio and historically have been supervised by the Commission. We do not suggest regulating Internet applications, much less the content of Internet communications. We also will not address in this proceeding other Internet facilities or services that currently are lightly regulated or unregulated, such as the Internet backbone, content delivery networks (CDNs), over-the-top video services, or voice-over-Internet-Protocol (VoIP) telephony services. Our questions instead are directed toward addressing broadband Internet service in a way that is consistent with the Communications Act, reduces uncertainty that may chill investment and innovation if allowed to continue, and accomplishes Congress's pro-consumer, pro-competition goals for broadband.

Discussion

Background

11. The Commission has long sought to ensure that communications networks support a robust marketplace for computer services operated over publicly accessible networks, from the early database lookup services to today's social networking sites. To provide context for the later discussion of the Commission's options for a suitable framework for broadband Internet service, we briefly describe this historical backdrop.

The Commission's Classification Decisions

12. In 1966, the Commission initiated its *Computer Inquiries* "to ascertain whether the services and facilities offered by common carriers are compatible with the present and anticipated communications requirements of computer users." In *Computer I,* the Commission required "maximum separation" between large carriers that offered data transmission services subject to common carrier requirements and their affiliates that sold data processing services. Refining this approach, in *Computer II* and *Computer III* the Commission required facilities-based providers of "enhanced services" to separate out and offer on a common carrier basis the "basic service" transmission component underlying their enhanced services.

13. In the Telecommunications Act of 1996, Congress built upon the *Computer Inquiries* by codifying the Commission's distinction between "telecommunications services" used to transmit information (akin to offerings of "basic services") and "information services" that run over the network (akin to "enhanced services"). In a 1998 report to Congress, the Commission attempted to indicate how it might apply the new law in the Internet context. Approximately 98 percent of households with Internet connections then used traditional telephone service to "dial up" their Internet access service provider, which was typically a separate entity from their telephone company. In the report to Congress—widely known as the "*Stevens Report,*" after Senator Ted Stevens—the Commission stated

that Internet access service as it was then being provided was an "information service." The *Stevens Report* declined to address whether entities that provided Internet connectivity over their own network facilities were offering a separate telecommunications component. The courts, rather than the Commission, first answered that question.

14. In 2000 the United States Court of Appeals for the Ninth Circuit held that cable modem Internet service is a telecommunications service to the extent that the cable operator "provides its subscribers Internet transmission over its cable broadband facility" and an information service to the extent the operator acts as a "conventional [Internet Service Provider (ISP)]." At the time, the Commission's *Computer Inquiry* rules required telephone companies to offer their digital subscriber line (DSL) transmission services as telecommunications services. The Ninth Circuit's decision thus put cable companies' broadband transmission service on a regulatory par with DSL transmission service.

15. In 2002, the Commission exercised its authority to interpret the Act and disagreed with the Ninth Circuit. Addressing the classification of cable modem service, the Commission observed that "[t]he Communications Act does not clearly indicate how cable modem service should be classified or regulated." Based on a factual record that had been compiled largely in 2000, the Commission's *Cable Modem Declaratory Ruling* described cable modem service as "typically includ[ing] many and sometimes all of the functions made available through dial-up Internet access service, including content, e-mail accounts, access to news groups, the ability to create a personal Web page, and the ability to retrieve information from the Internet, including access to the World Wide Web." The Commission noted that cable modem providers often consolidated these functions "so that subscribers usually do not need to contract separately with another Internet access provider to obtain discrete services or applications, such as an e-mail account or connectivity to the Internet, including access to the World Wide Web." The Commission defined cable modem service as "a service that uses cable system facilities to provide residential subscribers with high-speed Internet access, as well as many applications or functions that can be used with high-speed Internet access."

16. The Commission identified a portion of the cable modem service it called "Internet connectivity," which it described as establishing a physical connection to the Internet and interconnecting with the Internet backbone, and sometimes including protocol conversion, Internet Protocol (IP) address number assignment, domain name resolution through a domain name system (DNS), network security, caching, network monitoring, capacity engineering and management, fault management, and troubleshooting. The *Ruling* also noted that "[n]etwork monitoring, capacity engineering and management, fault management, and troubleshooting are Internet access service functions that are generally performed at an ISP or cable operator's Network Operations Center (NOC) or back office and serve to provide a steady and accurate flow of information between the cable system to which the subscriber is connected and the Internet." The Commission distinguished these functions from "Internet applications [also] provided through cable modem services," including "e-mail, access to online newsgroups, and creating or obtaining and aggregating content," "home pages," and "the ability to create a personal Web page."

17. The Commission found that cable modem service was "an offering . . . which combines the transmission of data with computer processing, information provision, and computer interactivity, enabling end users to run a variety of applications." The Commission further concluded that, "as it [was] currently offered," cable modem service as a whole met the statutory definition of "information service" because its components were best viewed as a "single, integrated service that enables the subscriber to utilize Internet access service," with a telecommunications component that was "not . . . separable from the data processing capabilities of the service." The Commission thus concluded that cable modem service "does not include an offering of telecommunications service to subscribers."

18. When the United States Supreme Court considered the *Cable Modem Declaratory Ruling* in the *Brand X* case, all parties agreed that cable modem service either *is* or *includes* an information service. The Court therefore focused, in pertinent part, on whether the Commission permissibly interpreted the Communications Act in concluding that cable modem service providers offer only an information service, rather than a separate telecommunications service and information service. The Court's opinion reaffirms that courts must defer to the implementing agency's reasonable interpretation of an ambiguous statute. Justice Thomas, writing for the six-Justice majority, recited that "ambiguities in statutes within an agency's jurisdiction to administer are delegations of authority to the agency to fill the statutory gap in reasonable fashion. Filling these gaps * * * involves difficult policy choices that agencies are better equipped to make than courts." Furthermore, "[a]n initial agency interpretation is not instantly carved in stone. On the contrary, the agency * * * must consider varying interpretations and the wisdom of its policy on a continuing basis."

19. Turning specifically to the Communications Act, Justice Thomas wrote: "[T]he statute fails unambiguously to classify the telecommunications component of cable modem service as a distinct offering. This leaves federal telecommunications policy in this technical and complex area to be set by the Commission." "The questions the Commission resolved in the order under review," Justice Thomas summed up, "involve a subject matter [that] is technical, complex, and dynamic. The Commission is in a far better position to address these questions than we are." Justice Breyer concurred with Justice Thomas, stating that he "believe[d] that the Federal Communications Commission's decision falls within the scope of its statutorily delegated authority," although "perhaps just barely."

20. In dissent, Justice Scalia, joined by Justices Souter and Ginsburg, expressed the view that the Commission had adopted "an implausible reading of the statute[,] * * * thus exceed[ing] the authority given it by Congress." Justice Scalia reasoned that "the telecommunications component of cable-modem service retains such ample independent identity that it must be regarded as being on offer—especially when seen from the perspective of the consumer or end user."

21. After the Supreme Court affirmed the Commission's authority to classify cable modem service, the Commission eliminated the resulting regulatory asymmetry between cable companies and other broadband Internet service providers by issuing follow-on orders that extended the information service classification to broadband Internet services offered over DSL and other wireline facilities, power lines, and wireless facilities. The Commission nevertheless allowed these providers, at their own discretion, to offer the broadband transmission component of their Internet service as a separate telecommunications service. Exercising that flexibility, providers—including more than 840 incumbent local

telephone companies—currently offer broadband transmission as a telecommunications service expressly separate from their Internet information service.

The Commission's Established Policy Goals

22. In the 1996 Act, Congress made clear its desire that the Commission promote the widespread availability of affordable Internet connectivity services, directing the Commission to adopt universal service mechanisms to ensure that "[a]ccess to advanced telecommunications and information services * * * [is] provided in all regions of the Nation." Congress also instructed the Commission to "encourage the deployment on a reasonable and timely basis of advanced telecommunications capability to all Americans." The Commission's classification decisions in the *Cable Modem Declaratory Ruling* and the later follow-on orders were intended to support the policy goal of encouraging widespread deployment of broadband. The Commission's hypothesis was that classifying all of broadband Internet service as an information service, outside the scope of any specific regulatory duty in the Act, would help achieve Congress' aims.

23. At the same time, the Commission acted with the express understanding that its information service classifications would not impair the agency's ability to protect the public interest. For example, when the Commission permitted telephone companies to offer broadband Internet service as solely an information service, it emphasized that this new classification would not remove the agency's "ample" Title I authority to accomplish policy objectives related to consumer protection, network reliability, and national security. The *Wireline Broadband Report and Order* thus was accompanied by a *Broadband Consumer Protection Notice,* in which the Commission sought comment on "a framework that ensures that consumer protection needs are met by *all* providers of broadband Internet access service, regardless of the underlying technology." The Commission stressed that its ancillary jurisdiction was "ample to accomplish the consumer protection goals we identify." The Commission similarly referenced the *Broadband Consumer Protection Notice* when it extended the information service classification to broadband Internet services offered over power lines and wireless facilities.

24. On the same day it adopted the *Wireline Broadband Report and Order* and *Broadband Consumer Protection Notice,* moreover, the Commission unanimously adopted the *Internet Policy Statement.* In this *Statement,* the Commission articulated four principles "[t]o encourage broadband deployment and preserve and promote the open and interconnected nature of the public Internet," and to "foster creation adoption and use of Internet broadband content, applications, services and attachments, and to insure consumers benefit from the innovation that comes from competition." The principles are:

- consumers are entitled to access the lawful Internet content of their choice;
- consumers are entitled to run applications and use services of their choice, subject to the needs of law enforcement;
- consumers are entitled to connect their choice of legal devices that do not harm the network; and
- consumers are entitled to competition among network providers, application and service providers, and content providers. All principles are subject to reasonable network management.

The Commission expressed confidence that it had the "jurisdiction necessary to ensure that providers of telecommunications for Internet access * * * are operated in a neutral manner."

Legal Developments

25. Recent legislative and judicial developments suggest a need to revisit the Commission's approach to broadband Internet service. Since 2008, Congress has passed three significant pieces of legislation that reflect its strong interest in ubiquitous deployment of high speed broadband communications networks and bear on the Commission's policy goals for broadband: the 2008 Farm Bill directing the Chairman to submit to Congress "a comprehensive rural broadband strategy," including recommendations for the rapid buildout of broadband in rural areas and for how federal resources can "best * * * overcome obstacles that impede broadband deployment"; the Broadband Data Improvement Act, to improve data collection and "promote the deployment of affordable broadband services to all parts of the Nation"; and the Recovery Act, which, among other things, appropriated up to $7.2 billion to evaluate, develop, and expand access to and use of broadband services, and required the Commission to develop the National Broadband Plan to ensure that every American has "access to broadband capability and * * * establish benchmarks for meeting that goal." In the Recovery Act, Congress further directed the Commission to produce a "detailed strategy for achieving affordability of such service and maximum utilization of broadband infrastructure and service by the public," and a "plan for [the] use of broadband structure and services" to advance national goals such as public safety, consumer welfare, and education. These three pieces of legislation, passed within a span of nine months, make clear that the Commission must retain its focus on implementing broadband policies that encourage investment, innovation, and competition, and promote the interests of consumers.

26. Even more recently, the D.C. Circuit's rejection of the Commission's attempt to address a broadband Internet service provider's unreasonable traffic disruption practices has cast a shadow over the Commission's prior understanding of its authority over broadband Internet services. In late 2007, the Commission received a complaint alleging that Comcast was blocking peer-to-peer traffic in violation of the *Internet Policy Statement.* In 2008, the Commission granted the complaint and directed Comcast to disclose specific information about its network management practices to the Commission, submit a compliance plan detailing how it would transition away from unreasonable network management practices, and disclose to the public the network management practices it intends to use going forward. Comcast challenged that decision in the D.C. Circuit, arguing (among other things) that the Commission lacks authority to prohibit a broadband Internet service provider from engaging in discriminatory practices that violate the four principles the Commission announced in 2005.

27. On April 6, 2010, the D.C. Circuit granted Comcast's petition for review and vacated the Commission's enforcement decision, holding that the Commission had "failed to tie its assertion of ancillary authority over Comcast's Internet service to any 'statutorily mandated responsibility.'" The Commission had argued that ending Comcast's secret practices was ancillary to the statutory objectives Congress established for the Commission in sections 1 and 230(b) of the Act. The court rejected that argument on the ground that those sections are merely statements of policy by Congress—as opposed to grants of regulatory authority—and thus were not sufficient to support Commission action against Comcast. The court also rejected the Commission's position that various

other statutory provisions supported ancillary authority. As to section 706 of the Telecommunications Act of 1996, the court noted that the agency had previously interpreted section 706 as not constituting a grant of authority and held that the Commission was bound by that interpretation for purposes of the case. The court also rejected the agency's reliance on sections 201, 256, 257, and 623 of the Communications Act.

Approaches to Classification

28. In light of the legislative and judicial developments described above, we seek comment on whether our existing legal framework adequately supports the Commission's previously stated policy goals for broadband. First, we ask whether the current information service classification of broadband Internet service can still support effective performance of the Commission's core responsibilities. Second, we ask for comment on the legal and practical consequences of classifying the Internet connectivity component of broadband Internet service as a "telecommunications service" to which the full weight of Title II requirements would apply, and whether such a classification would accurately reflect the current market facts. Finally, we identify and invite comment on a third way, under which the Commission would classify the Internet connectivity portion of broadband Internet service as a telecommunications service but would simultaneously forbear, using the section 10 authority Congress delegated to us, from all but a small handful of provisions necessary for effective implementation of universal service, competition and small business opportunity, and consumer protection policies.

29. The Commission has frequently expressed its commitment to protecting consumers and promoting innovation, investment, and competition in the broadband context. We reaffirm that commitment here and ask commenters to address—in general terms, as well as in response to the specific questions posed below—which of the three alternative regulatory frameworks for broadband Internet service (or what other framework) will best position the Commission to advance these fundamental goals. We note that because the broadband Internet service classification questions posed in this part II.B involve an interpretation of the Communications Act, the notice and comment procedures we follow here are not required under the Administrative Procedure Act. In order to provide the greatest possible opportunity for public comment, however, we are soliciting initial and reply comments via the traditional filing mechanisms, as well as input through our recently expanded online participation tools.

Continued Information Service Classification and Reliance on Ancillary Authority

30. In this part, we seek comment on maintaining the current classification of wired broadband Internet service as a unitary information service. Under this approach, we would rely primarily on our ancillary authority to implement the Commission's broadband policies. We seek comment on whether our ancillary authority continues to provide an adequate legal foundation. Throughout the last decade, the Commission has stated its consistent understanding that Title I provided the Commission adequate authority to support effective performance of its core responsibilities. Commissioners, including the two former Chairmen who urged the information service approach, as well as cable and telephone companies and other interested parties, individually expressed this understanding. In *Brand X,* the Supreme Court appeared to confirm this widely held view, stating that "the Commission remains free to impose special regulatory duties on facilities-based ISPs under its Title I ancillary jurisdiction." The *Comcast* decision, however, causes us to reexamine our ability to rely on Title I as the legal basis for implementing broadband policies.

31. Some have suggested that although the D.C. Circuit rejected the Commission's theory of ancillary authority in *Comcast,* the Commission can still accomplish many of its most important broadband-related goals without changing its classification of broadband Internet service as a unitary information service. We seek comment on the overall scope of the Commission's authority regarding broadband Internet service in the wake of the *Comcast* decision. Below we identify and seek comment on several particular concerns.

Universal Service

32. Can the Commission reform its universal service program to support broadband Internet service by asserting direct authority under section 254, combined with ancillary authority under Title I? AT&T, for example, observes that section 254 provides that "[a]ccess to advanced telecommunications *and information services* should be provided in all regions of the nation," and that the Commission's universal service programs "shall" be based on this and other enumerated principles. AT&T notes that the Commission's information service classification for broadband Internet service creates "tension" with "the text of Section 254(c)(1), which states that '[u]niversal service is an evolving level of *telecommunications services* that the Commission shall establish periodically under this section.' " But, AT&T suggests, "[o]ther evidence in the statutory text makes clear that Congress did not intend to disable the Commission from using universal service to support information services." For example,

- "Section 254(b) *requires* the Commission to use universal service to promote access to 'advanced telecommunications and information services,' "
- "Section 254(c) * * * [refers] to an '*evolving* level of telecommunications services that the Commission shall establish periodically under this section[,]' " and
- Section 254(c)(2) "expressly authoriz[es] the Joint Board and the Commission to 'modif[y] * * * the definition of the *services* that are supported by Federal universal support mechanisms.' " The reference to "services" in section 254(c)(2) may suggest that Congress intended universal service policies to support information services, even though the definition of universal service in section 254(c)(1) is explicitly limited to "telecommunications services."

AT&T explains that section 254 "contains competing directives," but asserts that "the schizophrenic nature of Section 254 is simply another example of the many ways in which the 1996 Act is not a 'model of clarity.' "

33. We seek comment on whether we may interpret section 254 to give the Commission authority to provide universal service support for broadband Internet service if that service is classified as a unitary information service. Could we provide support to information service providers consistent with section 254(e), which says that "only an eligible telecommunications carrier designated under section 214(e) shall be eligible to receive specific Federal universal service support," and 214(e), which sets forth the framework for designating "telecommunications carrier[s] * * * eligible to receive universal service support"?

34. AT&T posits that even after the *Comcast* decision, the Commission could bolster its reliance on section 254 by also relying on several other provisions of the Act. First, the "necessary and proper clause" in section

4(i) of the Act allows the Commission to "perform any and all acts, make such rules and regulations, and issue such orders, not inconsistent with this chapter, as may be necessary in the execution of its functions." Second, the Act makes clear that the Commission's "core statutory mission" is to "make available, so far as possible, to all the people of the United States * * * a rapid, efficient, Nation-wide and world-wide wire and radio communication service with adequate facilities at reasonable charges." Third, the text of 254, as described above, suggests that Congress intended the Commission to support universal broadband Internet service. Finally, the policy directive in section 706 of the 1996 Act instructs the Commission to encourage the deployment on a reasonable and timely basis of advanced telecommunications capability to all Americans. AT&T contends that section 706's directive supports the view that section 254 provides authority for supporting broadband Internet services with monies from the Universal Service Fund. We seek comment on AT&T's analysis.

35. The National Cable and Telecommunications Association (NCTA) has put forward a similar legal theory rooted in section 254(h)(2) of the Communications Act. That section gives the Commission authority "to enhance * * * access to advanced telecommunications and information services for all public and non-profit elementary and secondary school classrooms, health care providers, and libraries." NCTA contends that because "the use of broadband in the home has become a critical component of the American education system * * * it is entirely reasonable to read the statutory directive to support Internet access for classrooms to include support for residential broadband service to households where it is reasonably likely that such service would be used for educational purposes." Could the Commission interpret section 254(h)(2) to permit this type of support for broadband Internet service? Is this approach a permissible extension of the Commission's existing E–Rate program? Would this approach enable the Commission to provide support for broadband Internet service only to households with school-aged children, or could the Commission provide support for adult education as well?

36. Another legal theory for promoting broadband deployment under the Commission's current classification of broadband Internet service rests directly on section 706 of the 1996 Act. Section 706(a) states that the Commission "shall encourage the deployment on a reasonable and timely basis of advanced telecommunications capability to all Americans * * * by utilizing, in a manner consistent with the public interest, convenience, and necessity, price cap regulation, regulatory forbearance, measures that promote competition in the local telecommunications market, or other regulating methods that remove barriers to infrastructure investment." Section 706(c) defines "advanced telecommunications capability" as "high-speed, switched, broadband telecommunications capability that enables users to originate and receive high-quality voice, data, graphics, and video telecommunications using any technology." The D.C. Circuit rejected section 706(a) as a basis for the Commission's *Comcast* order because "[i]n an earlier, still-binding order * * * the Commission ruled that section 706 'does not constitute an independent grant of authority,'" and "agencies 'may not * * * depart from a prior policy *sub silentio.'*" We seek comment on whether the Commission should revisit and change its conclusion that section 706(a) is not an independent grant of authority. What findings would be necessary to reverse that interpretation? If the Commission were to find that section 706(a) is an independent grant of authority, would that subsection, read in conjunction with sections 4(i) and 254, provide a firm basis for the Commission to provide universal service support for broadband Internet services?

37. Some parties have suggested that the Commission could rely on section 706(b) as a source of authority to support broadband Internet service with Universal Service Fund money. That section provides that:

> [t]he Commission shall * * * annually * * * initiate a notice of inquiry concerning the availability of advanced telecommunications capability to all Americans * * * . In the inquiry, the Commission shall determine whether advanced telecommunications capability is being deployed to all Americans in a reasonable and timely fashion. If the Commission's determination is negative, it shall take immediate action to accelerate deployment of such capability by removing barriers to infrastructure investment and by promoting competition in the telecommunications market.

We seek comment on whether we could interpret section 706(b) as an independent grant of authority. Specifically, we ask whether Congress's direction that the Commission take "immediate action" if it makes a negative determination about the state of broadband deployment authorizes the Commission to provide universal service support to spur that deployment. Would any such support be contingent on continued negative findings in the annual broadband availability inquiry? Under section 706(b), would universal service programs have to be tailored to particular geographic areas where deployment is lagging, or could the Commission implement the program on a national basis? Would the Commission be limited to direct support for deployment, or could the Commission interpret section 706(b) also to support broadband Internet services to low-income populations, such as is the case with our support for voice services in the Lifeline and Link Up programs?

38. For each of these legal theories, the Commission seeks comment on the administrative record that would be needed to successfully defend against a legal challenge to implementation of the theory. Would adopting these theories be consistent with the federal Anti-Deficiency Act and Miscellaneous Receipts Act? What other issues should the Commission consider in evaluating these legal theories? Are there other legal frameworks that would allow us to promote universal service in the broadband context without revisiting our classification decisions?

Privacy

39. The Commission has long supported protecting the privacy of users of broadband Internet services. In 2005, the Commission emphasized in the *Wireline Broadband Report and Order* that "[c]onsumers' privacy needs are no less important when consumers communicate over and use broadband Internet access than when they rely on [telephone] services." The Commission believed at the time that it had jurisdiction to enforce privacy requirements, and "note[d] that long before Congress enacted section 222 of the Act," which requires providers of telecommunications services to protect confidential information, "the Commission had recognized the need for privacy requirements associated with the provision of enhanced services." In 2007, the Commission extended the privacy protections of section 222 to interconnected VoIP services without resolving whether interconnected VoIP services are telecommunications services or information services. More recently, the National Broadband Plan recommended that the Commission work with the Federal Trade Commission (FTC) to protect consumers' privacy in the broadband context. Indeed, we fully intend that our efforts with regard to

privacy complement those of the FTC. We seek comment on the best approach for ensuring privacy for broadband Internet service users under the Commission's current information service classification, and any legal obstacles to protecting privacy that may exist if the Commission retains that classification.

Access for Individuals With Disabilities

40. Section 255 requires telecommunications service providers and equipment manufacturers to make their services and equipment accessible to individuals with disabilities, unless not readily achievable. Section 251(a)(2) requires telecommunications carriers "not to install network features, functions, or capabilities that do not comply with the guidelines and standards established pursuant to section 255." In the 2005 *Wireline Broadband Report and Order,* the Commission committed to exercise its authority "to ensure achievement of important policy goals of section 255" in the broadband context. In 2007, the Commission exercised its ancillary authority to extend section 255 to interconnected VoIP providers, and in 1999 the Commission similarly relied on ancillary authority to extend disability-related requirements to voicemail and interactive menu services. The Commission also exercised ancillary authority to extend section 225 telecommunications relay service obligations under the Commission's rules to providers of interconnected VoIP. More recently, a unanimous Commission stated its belief that disabilities should not stand in the way of Americans' "opportunity to benefit from the broadband communications era." The Commission has also announced its intent to consider how "[t]o better enable Americans with disabilities to experience the benefits of broadband." We seek comment on the best legal approaches to extending disability-related protections to broadband Internet service users under the Commission's current information service classification. Could we exercise ancillary authority to ensure access for people with disabilities? Could the Commission rely on the mandate in section 706(a) to "encourage the deployment on a reasonable and timely basis of advanced telecommunications capability to *all* Americans," or the similar directive in section 706(b)?

Public Safety and Homeland Security

41. As noted above, Congress created the Commission, in part, "for the purpose of the national defense, [and] for the purpose of promoting safety of life and property through the use of wire and radio communications." *Comcast* did not address questions of national defense, public safety, homeland security, or national security. Are there bases for asserting ancillary authority over broadband Internet service providers for purposes of advancing such vital and clearly enumerated Congressional purposes? Could the Commission use its ancillary authority as a legal foundation for protecting cyber security and other public safety initiatives, such as 911 emergency and public warning and alerting services, with respect to broadband Internet service? Specifically, could the Commission rely on provisions in Title I either alone or in combination with provisions in Title II or Title III to support these public safety purposes, as well as data reporting and/or network reliability and resiliency standards with respect to broadband Internet services? As noted below, Title III contains several provisions that enable the Commission to impose on spectrum licensees obligations that are in the public interest. With the convergence of the various modes of communications networks, many broadband Internet services incorporate wireline and wireless elements. What would be the effect if the Commission employed its Title III authority to achieve public safety goals with respect to wireless elements of such converged services? Could the Commission also regulate wireline elements of such services through its Title III and Title I authority because of the wireless elements incorporated into these services, or in the interests of ensuring regulatory parity and predictability? Could the Commission rely on the mandate in section 706(a) to "encourage the deployment on a reasonable and timely basis of advanced telecommunications capability to all Americans" to ensure the security, reliability and resiliency of wired broadband Internet services, or to advance other public safety and homeland security initiatives?

Addressing Harmful Practices by Internet Service Providers

42. Although the D.C. Circuit rejected the legal theory the Commission relied on to address Comcast's interference with its customers' peer-to-peer transmissions, some have suggested that other theories of ancillary authority could support Commission action to protect against harmful practices of this sort. For example, one commentator has proposed that the Commission assert ancillary authority pursuant to sections 251(a) and 256 of the Act, which address interconnection by telecommunications carriers. Although these provisions apply specifically to telecommunications carriers, the proposal asserts that they are not explicitly limited to the telecommunications services provided by such carriers.

43. Section 251(a) requires each carrier "to interconnect directly or indirectly with the facilities and equipment of other telecommunications carriers." Reading section 251(a) as limited to telecommunication services, it has been suggested, "would make [the Commission's] rules promoting interconnection irrelevant" as the major carriers move increasingly toward providing services over broadband Internet networks. Likewise, "[i]n a world where traditional public telecommunications networks and newer Internet-data-transmission networks are pervasively interconnected," it has been asserted, "it makes no sense to preclude the FCC's interoperability efforts [pursuant to section 256] from affecting information services."

44. We seek comment on this reasoning. What factual findings would the Commission have to make to support reliance on sections 251(a) and/or 256 with respect to broadband Internet service? Would those facts support exercise of authority sufficient to implement the Commission's broadband policies in full, or in part? Under this approach, could the Commission address conduct by broadband Internet service providers that are not also telecommunications carriers? Does reliance on sections 251(a) and 256 limit Commission authority to protect competition and consumers to only those networks that are interconnected with the public telephone network? If so, what are the practical implications of this limitation? What is the significance of the *Comcast* decision, which held that "[t]he Commission's attempt to tether its assertion of ancillary authority to section 256" was flawed in that context because section 256 states that "[n]othing in this section shall be construed as expanding or limiting any authority that the Commission" otherwise has under law? What else should the Commission consider as it evaluates the significance of sections 251(a) and 256 in this proceeding?

45. Section 202(a) of the Communications Act makes it unlawful for any common carrier to make any unjust or unreasonable discrimination in charges, practices, classifications, regulations, facilities, or services for or in connection with like communication

service, directly or indirectly, by any means or device, or to make or give any undue or unreasonable preference or advantage to any particular person, class of persons, or locality, or to subject any particular person, class of persons, or locality to any undue or unreasonable prejudice or disadvantage.

It has been suggested that "[i]f network operators are allowed the option of offering broadband Internet access services on a completely unregulated basis, that option could enable them to end run Section 202(a)" as carriers move toward providing services over broadband Internet networks, "and render that provision a dead letter." We seek comment on the factual and legal assumptions underlying this argument, and whether this reasoning provides the Commission authority to address practices of broadband Internet service providers that endanger competition or consumer welfare.

46. As the Commission argued to the D.C. Circuit in the *Comcast* case, section 706(a) might also provide a basis for prohibiting harmful practices of Internet service providers. As noted above, the D.C. Circuit gave no weight to section 706(a) because the Commission had determined in a prior order that section 706(a) is not an independent grant of authority. We seek comment on the best reading of section 706(a). We also seek comment on whether section 706(b) could provide a legal foundation for rules addressing harmful practices by Internet service providers. If so, could the Commission adopt such rules on a national basis, or would it have to tailor its rules to particular geographic areas? Would its rules depend on continued negative determinations in the annual broadband availability report?

47. The *Comcast* opinion also rejected arguments that other provisions of Titles II, III, and VI of the Communications Act supported the Commission's action against Comcast because Internet-enabled communications services that depend on broadband Internet service—such as VoIP and Internet video services—may affect the regulated operations of telephony common carriers, broadcasters, and cable operators. The court did not address the merits of these theories, but rather rejected them because they were not sufficiently articulated in the underlying Commission order. Could such theories provide sufficient support for the Commission to address harmful practices of Internet service providers? What type of factual record would be required to support such theories? If the Commission relied on these theories, could it prohibit behavior—such as the covert blocking of online gaming or e-commerce services, perhaps—that does not obviously affect services clearly addressed by Titles II, III, or VI? Could the Commission rely on sections 624 or 629 of the Act to establish broadband policy related to cable modem service?

48. We also invite comment on whether the portions of section 214(a) addressing discontinuance, reduction, and impairment of service provide a potential basis for an assertion of ancillary authority regarding harmful Internet service provider practices. That provision mandates that a common carrier may not "impair service to a community" without prior Commission approval. Impairment, in the section 214(a) context, refers to both "the adequacy" and "quality" of the service provided.

49. Are there other statutory provisions that could support the Commission's exercise of ancillary authority in this area? Do any statutory provisions preclude such action if the Commission retains its information service classification?

50. Other harmful practices by broadband Internet service providers may involve a failure to disclose practices to consumers. For instance, one problem identified by the Commission in the *Comcast* case was Comcast's failure to identify to customers its practice of degrading peer-to-peer traffic. If the Commission maintains its information services framework for broadband Internet services, will it have sufficient authority to address these concerns?

Other Approaches to Oversight

51. Finally, we ask for public input on whether there are other approaches to fulfilling our role for broadband Internet services that would provide meaningful oversight consistent with maintaining robust incentives for innovation and investment. For instance, in a number of proceedings commenters have suggested that the Commission should pursue policies based on standards set by third parties and enforced by the Commission. In the Open Internet proceeding, Verizon and Google suggest that the Commission could create technical advisory groups "comprised of a range of stakeholders with technical expertise" to develop best practices, resolve disputes, issue advisory opinions, and coordinate with standards-setting bodies. Although Verizon and Google "may not necessarily agree on which federal agency does or should have authority over these matters," they "do recognize as a policy matter that there should be some backstop role for federal authorities to prevent harm to competition and consumers if or when bad actors emerge anywhere in the Internet space, and * * * agree that involvement should occur only where necessary on a case-by-case base basis." Commenters in other proceedings have suggested similar approaches. We ask commenters to address whether the Commission should pursue a regime in which one or more third parties play a major role in setting standards and best practices relative to maintaining our policy goals for broadband Internet service. Pursuant to what authority could the Commission create a third party advisory group? What authority could the Commission delegate to such a third party or third parties? Would it be appropriate for other federal governmental entities, such as the FTC, to have a role in such an approach? Would the Commission have sufficient ancillary authority under its information service framework to serve as a backstop if the third party is unable to resolve a dispute or implement a necessary policy?

Application of All Title II Provisions

52. Title II of the Communications Act provides the Commission express authority to implement, for telecommunications services, rules furthering universal service, privacy, access for persons with disabilities, and basic consumer protection, among other federal policies. We seek comment on whether the legal and policy developments discussed above and the facts of today's broadband marketplace suggest a need to classify Internet connectivity as a telecommunications service, so as to trigger this clear authority. We also ask whether that approach would be consistent with our goals of promoting innovation and investment in broadband, or would result in overregulation of a service that has undergone rapid and generally beneficial development under our deregulatory approach.

Current Facts in the Broadband Marketplace

53. In the *Cable Modem Declaratory Ruling,* the Commission observed that "the cable modem service business is still nascent, and the shape of broadband deployment is not yet clear," and nearly a decade has passed since the Commission examined the facts surrounding broadband Internet service in the *Cable Modem Declaratory Ruling.* In this part we therefore ask whether or not the facts of today's broadband marketplace support a conclusion that providers now offer Internet connectivity as a separate

telecommunications service. In addition to the specific questions we ask below, we seek comment on what facts are most relevant to this inquiry. The Commission has explained that because the Act defines "telecommunications service" as " 'the *offering* of telecommunications for a fee directly *to the public*[,]' * * * whether a telecommunications service is being provided turns on what the entity is 'offering * * * to the public,' and customers' understanding of that service." Similarly, in *Brand X,* the majority opinion noted that "[i]t is common usage to describe what a company 'offers' to a consumer as what the consumer perceives to be the integrated finished product." The *Brand X* dissent asserted that "[t]he relevant question is whether the individual components in a package being offered still possess sufficient identity to be described as separate objects of the offer, or whether they have been so changed by their combination with the other components that it is no longer reasonable to describe them in that way." The *Brand X* majority opinion and the dissent examined consumers' understanding of the services, analogies to other services, and technical characteristics of the services being provided. What factors should the Commission consider in order to assess the proper classification of broadband Internet connectivity service?

54. *Status of Current Offerings.* Is wired broadband Internet service (or any telecommunications component thereof) held out "for a fee directly to the public, or to such classes of users as to be effectively available directly to the public," for instance through a tariff such as the NECA DSL Access Service Tariff or through facilities-based Internet service providers' public Web sites? A provider is engaged in common carriage if it "make[s] capacity available to the public indifferently"; it can be compelled to offer a common carriage service if "the public interest requires common carrier operation of the proposed facility." If so, we seek specific examples of such offerings. If not, does the Commission have legal authority to compel the offering of a broadband Internet telecommunications service that is not currently offered? If legal authority exists, would it be appropriate for the Commission to exercise such authority? Are there First Amendment constraints on the Commission's ability to compel the offering of such a service? Would such a compulsion raise any concerns under the Takings Clause of the Fifth Amendment?

55. *Services Offered Today.* When the Commission gathered the record for its classification orders, broadband Internet service was offered with various services—such as e-mail, newsgroups, and the ability to create and maintain a web page—that we described as "Internet applications." The Commission understood that subscribers to broadband Internet services "usually d[id] not need to contract separately" for "discrete services or applications" such as e-mail. We seek comment on whether this remains the case. To what extent are these and other applications and services sold with wired broadband Internet service today? Are providers offering the same applications and services that they did when the Commission began building the record in 2000, or have their offerings changed? Are these applications and services always packaged with Internet connectivity, or can consumers choose not to purchase them? What test(s) should the Commission use to evaluate whether particular features are today integrated with the underlying Internet connectivity?

56. *Consumer Use and Perception.* Next, we seek comment on how consumers use and perceive broadband Internet service. Do customers today perceive that they are receiving one unitary service comprising Internet connectivity as well as features and functionalities, or Internet connectivity as the main service, with additional features and functionalities simultaneously offered and provided? We note that under Commission precedent, services composing a single bundle at the point of sale—for instance, local telephone service packaged with voice mail—can retain distinct identities as separate offerings for classification purposes. To what extent do consumers continue to rely on the features and applications that are provided as part of their broadband Internet service package, and to what extent have they increased their use of applications and services offered by third party providers? For instance, some users now rely on free e-mail services provided by companies such as Yahoo and Microsoft, social networking sites including Facebook and MySpace, public message boards like those found in the Google Groups service, web portals like Netvibes, web hosting services like Go Daddy, and blog hosting services like TypePad. How does the use of these third party services compare with the use of similar services offered by broadband Internet service providers? To what extent do consumers rely on their Internet service provider or other providers for security features and spam filtering? To what extent do consumers rely on their Internet service provider, as opposed to alternative providers, for content such as news and medical advice? To the extent broadband Internet service providers offer applications to consumers, do consumers view them as an integrated part of the Internet connectivity offering? To what extent do consumers today use "the high-speed wire always in connection with the information-processing capabilities provided by Internet access"?

57. *Marketing Practices.* We also seek comment on how broadband Internet service providers market their services. What do broadband Internet service providers' marketing practices suggest they are offering to the public? What features do broadband Internet service providers highlight in their advertisements to consumers? How do the companies describe their services? What are the primary dimensions of competition among broadband Internet service providers? Are cable modem and other wired services marketed or understood differently from each other, or in a generally similar way?

58. *Technical and Functional Characteristics.* In addition, to aid our understanding of what carriers offer to consumers, we seek to develop a current record on the technical and functional characteristics of broadband Internet service, and whether those characteristics have changed materially in the last decade. For example, DNS lookup is now offered to consumers on a standalone basis, and web page caching is offered by third party content delivery networks. Web browsers, for example, are often installed separately by users. We ask commenters to describe the technical characteristics of broadband Internet service, including identifying those functions that are essential for web browsing and other basic consumer Internet activities. What are the necessary components of web browsing? How is caching provided to end users, and how have caching services changed over time? How do routing functions and DNS directory lookup enable users to access information online?

59. In classifying services, the Commission has taken into account the purpose of the feature or service at issue. For example, some features and services that meet the literal definition of "enhanced service," but do not alter the fundamental character of the associated basic transmission service, are "adjunct-to-basic" and are treated as basic (*i.e.,* telecommunications) services even though they go beyond mere transmission. Do any of the features and

functionalities offered by broadband Internet service providers have relevant similarities to or differences from those that resemble an information service but are treated differently under Commission precedent? Similarly, which, if any, of the "Internet connectivity" functions listed in the *Cable Modem Declaratory Ruling* fall within the management exceptions to the information services category, and why?

60. Some have suggested that the Commission should take account of the different network "layers" that compose the Internet. Are distinctions between the functional "layers" that compose the Internet relevant and useful for classifying broadband Internet service? For example, the Commission could distinguish between physical, logical, and content and application layers, and identify some of those layers as elements of a telecommunications service and others as elements of an information service. (As discussed above, the Commission historically has distinguished between Internet connectivity functions and Internet applications.) If the Commission adopted this approach, which of the services offered by wired broadband Internet service providers should be included in each category? Are the boundaries of each layer sufficiently clear that such an approach would be workable in practice? Would such an approach have implications for services other than broadband Internet service?

61. *Competition.* We also seek comment on the level of competition among broadband Internet service providers. The Commission adopted the unitary information service classification for broadband Internet services in part "to encourage facilities-based competition." The Commission envisioned competition among cable operators, telephone companies, satellite providers, terrestrial wireless providers, and broadband-over-powerline (BPL) providers. Has the market for broadband Internet services developed as expected, and, if not, what is the significance for this proceeding of the market's actual development?

62. Are there other relevant facts or circumstances that bear on the Commission's application of the statutory definition of "telecommunications service" to wired broadband Internet service?

Defining the Telecommunications Service

63. If the Commission were to classify a service provided as part of the broadband Internet service bundle as a telecommunications service, it would be necessary to define what is being so classified. Here we ask commenters to propose approaches to defining the telecommunications service offered as part of wired broadband Internet service, assuming that the Commission finds a separate telecommunications service is being offered today, or must be offered.

64. We have previously defined "Internet connectivity" to include the functions that "enable [broadband Internet service subscribers] to transmit data communications to and from the rest of the Internet." Identifying a telecommunications service at a similarly high level—for instance, as the service that provides Internet connectivity—may be appropriate for this proceeding if a telecommunications service is classified. Is this approach or some other mechanism appropriate to give the Internet service provider latitude to define its own telecommunications service? For instance, would it be desirable for the Commission to identify only bare minimum characteristics of an Internet connectivity service? Or is it necessary for the Commission to define the functionality, elements, or endpoints of Internet connectivity service? What are the pros and cons of these and other approaches? Would use of the term "Internet connectivity service" in this context be unduly confusing because the Commission has previously defined that term to include the function of "operating or interconnecting with Internet backbone facilities" in order to "enable cable modem service subscribers to transmit data communications to and from the rest of the Internet"?

65. Commenters should also identify the particular aspects of broadband Internet service that do and do not constitute "transmission, between or among points specified by the user, of information of the user's choosing, without change in the form or content of the information as sent and received." Does the catalog of Internet connectivity functions provided in the *Cable Modem Declaratory Ruling* include all the functions an end user would need from its broadband Internet service provider in order to use the Internet? Are there other connectivity functions the Commission should consider? Can the Commission draw guidance from other attempts to define the functionality of an Internet connectivity service, such as the definition in NECA's DSL Access Service Tariff? In its tariff, NECA offers a DSL data telecommunications service to end user and Internet service provider customers. The service "enables data traffic generated by a customer-provided modem to be transported to a DSL Access Service Connection Point using the Telephone Company's local exchange service facilities." The Access Service Connection Point is a point designated by the telephone company that "aggregates ADSL Access Service and/or wireline broadband Internet transmission service data traffic from and to suitably equipped Telephone Company Serving Wire Centers."

Consequences of Classifying Internet Connectivity as a Telecommunications Service

66. If we were to classify Internet connectivity service as a telecommunications service and take no further action, that service would be subject to all requirements of Title II that apply to telecommunications service or common carrier service. If the Commission chose, it could provide support for Internet connectivity services through the Universal Service Fund under section 254. Under section 222, the Commission could ensure that consumers of Internet connectivity enjoy protections for their private information. Consumers with disabilities would see greater accessibility of broadband services and equipment under section 255. And the Commission could protect consumers and fair competition through application of sections 201, 202, and 208. Would application of all Title II requirements to the wired broadband Internet connectivity service be consistent with the approach to broadband Internet service described in part II.A.2, above? We seek comment on whether these benefits to classifying Internet connectivity as a telecommunications service would outweigh the costs of doing so, including the application of numerous regulatory provisions that the Commission, in its information service classification orders, determined should not apply. Are there any elements of our framework that the Commission could not pursue if it adopted a Title II classification? Under Title II classification what role, if any, might be played by third party standard setting bodies?

Telecommunications Service Classification and Forbearance

67. In addition to the traditional information service and telecommunications service approaches discussed above, we identify and seek comment on a third option for establishing a suitable legal foundation for broadband Internet and Internet connectivity services. This third way

would involve classifying wired broadband Internet connectivity as a telecommunications service (as suggested above), but simultaneously forbearing from applying most requirements of Title II to that connectivity service, save for a small number of provisions.

68. Specifically, if the Commission decided, after appropriate analysis, to classify wired broadband Internet connectivity (and no other component of wired broadband Internet service) as a telecommunications service, it could simultaneously forbear from applying all but a handful of core statutory provisions—sections 201, 202, 208, and 254—to the service. Two other provisions that have attracted longstanding and broad support in the broadband context—sections 222 and 255—might also be implemented for the connectivity service, perhaps after the Commission provides guidance in subsequent proceedings as to how they will apply in this context. We seek comment on this third approach, and whether it would constitute a framework for broadband Internet service that is fundamentally consistent with what the Commission, Congress, consumer groups, and industry believed the Commission could pursue under Title I before the *Comcast* decision.

Forbearing To Maintain the Deregulatory Status Quo

69. In recognition of the need to tailor the Commission's policies to evolving markets and technologies, Congress gave the Commission in 1996 the authority and responsibility to forbear from applying provisions of the Communications Act when certain criteria are met, and specifically directed the Commission to use this new power to "encourage the deployment on a reasonable and timely basis of advanced telecommunications capability to all Americans." In typical forbearance proceedings, a petitioner—usually a telecommunications service provider—files a petition seeking relief from a provision of the Act that applies to it. The Commission "shall" grant the requested relief if:

(a) Enforcement of such regulation or provision is not necessary to ensure that the charges, practices, classifications, or regulations by, for, or in connection with that telecommunications carrier or telecommunications service are just and reasonable and are not unjustly or unreasonably discriminatory;

(b) enforcement of such regulation or provision is not necessary for the protection of consumers; and

(c) forbearance from applying such provision or regulation is consistent with the public interest.

In ordinary forbearance proceedings, therefore, the Commission must make a predictive judgment whether, without enforcement of the provisions or regulations in question, charges and practices will be just and reasonable, consumers will be protected, and the public interest will be served.

70. The forbearance analysis here has a different posture. The Commission would not be responding to a carrier's request to change the legal and regulatory framework that currently applies. Rather, it would be assessing whether to forbear from provisions of the Act that, because of our information service classification, *do not apply* at the time of the analysis. Under section 10, the Commission may forbear on its own motion. If the statutory criteria are met, the Commission is compelled to forbear just as if it were responding to a carrier's petition. In this situation, could the Commission simply observe the current marketplace for broadband Internet services to determine whether enforcing the currently inapplicable requirements is or is not necessary to ensure that charges and practices are just and reasonable and not unjustly or unreasonably discriminatory, whether application of the requirements is or is not necessary for the protection of consumers, and whether applying the requirements is or is not in the public interest? Section 10 allows the Commission to consider forbearance from requirements that do not currently apply or may not apply even in the absence of forbearance.

Identifying the Relevant Telecommunications Service and Telecommunications Carriers

71. In this part of the Notice we assume, solely for purposes of framing the forbearance option, that the Commission has decided to classify the Internet connectivity service underlying broadband Internet service as a telecommunications service. Section 10 provides that "the Commission shall forbear from applying any regulation or any provision of this chapter to a telecommunications carrier or telecommunications service, or class of telecommunications carriers or telecommunications services" if certain criteria are met. The relevant "telecommunications service" would be Internet connectivity service as the Commission defines it. The "class of telecommunications carriers" at issue would comprise the providers of the Internet connectivity service identified as a telecommunications service.

72. In this proceeding, however, we do not intend to disrupt the status quo for incumbent local exchange carriers or other common carriers that choose to offer their Internet transmission services as telecommunications services. Nor do we propose to alter the status quo with regard to the application of section 254(k) and related cost-allocation rules to these carriers. We therefore seek comment on excepting from forbearance any carrier that elects to be subject to the full range of Title II requirements, and on the mechanism that would be most suitable for a carrier to make such an election.

Defining the Geographic Scope for Analysis

73. Section 10 requires the Commission to forbear from unnecessary requirements "in any or some of [carriers'] geographic markets." By its terms section 10 requires no "particular * * * level of geographic rigor," and the Commission has flexibility to adopt an approach suited to the circumstances. The Commission decisions classifying broadband Internet service did not rely on any particular, defined geographic area. Instead, where those decisions evaluated the state of the marketplace, they did so "in view of larger trends." The 2005 *Wireline Broadband Report and Order* granted forbearance on a nationwide basis. The Commission has adopted a similar approach to evaluating the broadband marketplace in other forbearance decisions. Given that backdrop, and the fact that the forbearance discussed here would be designed to maintain a deregulatory status quo for wired broadband Internet service that applies across the nation, the same approach may be warranted here, with the effect that forbearance would be granted or denied on a nationwide basis. We seek comment on this approach. If commenters suggest a more granular geographic market as is sometimes used in other forbearance proceedings, we ask them to address whether such an approach would be legally required.

Identifying the Provisions of Title II From Which the Commission Would Forbear

74. The forbearance option contemplates a determination not to apply all but the small number of provisions of Title II that provide a solid legal foundation for the Commission to implement its established broadband policies. In this part, we seek comment on declining to forbear from the three core provisions of Title II—sections 201, 202, and 208. We also seek comment on whether we should decline to forbear

from section 254 in order to ensure that the Commission has clear authority to pursue universal service goals for broadband services. And we seek comment on whether we should decline to forbear from two other provisions—sections 222 and 255—that speak to two other broadband issues the Commission has believed it can address (customer privacy and access by persons with disabilities). We further seek comment on whether forbearing from any of the remaining provisions of Title II is beyond our forbearance authority or otherwise should be rejected.

75. *Exclusions from Forbearance: Sections 201, 202, and 208.* The Commission has never exercised its authority under section 10 to forbear from these three fundamental provisions of the Act, although it has been asked to do so on many occasions. In addition to being consistent with our precedent, a determination not to forbear from these core provisions would comport with Congress's approach to commercial mobile radio services (CMRS), such as cell phone services. In 1993, CMRS services were still nascent, and Congress specified in a new section 332(c)(1)(A) of the Communications Act that although Title II applies to CMRS, the Commission may forbear from enforcing any provision of the title *other* than sections 201, 202, and 208. After Congress gave the Commission broader forbearance authority in the Telecommunications Act of 1996, the Commission considered a petition to forbear from sections 201 and 202 as applied to certain CMRS services. The Commission rejected that forbearance request, finding that even in a competitive market those provisions are critical to protecting consumers.

76. Applying sections 201 and 202 could provide the Commission direct statutory authority to protect consumers and promote fair competition, yet allow the Commission to avoid burdensome regulation. For example, while CMRS providers are subject to sections 201 and 202, they do not file tariffs because the Commission forbore from section 203. We seek comment on these issues as well as how to address in any forbearance analysis the existing agency rules that have been promulgated under sections 201 and 202.

77. In addition, we seek comment on not forbearing from section 208 and the associated procedural rules. Would the enforcement regime that would apply if we enforce only section 208 be sufficient if we decide to forbear from the damages and jurisdictional provisions of sections 206 (carrier liability for damages), 207 (recovery of damages and forum election), and 209 (damages awards)? Would forbearance from these additional provisions render enforcement under section 208 procedurally or substantively deficient, or would section 208 (together with Title V of the Act) provide the Commission adequate authority to identify and address unlawful practices involving broadband Internet service?

78. *Exclusion from Forbearance: Section 254.* Section 254, the statutory foundation of our universal service programs, requires the Commission to promote universal service goals, including "[a]ccess to advanced telecommunications and information services * * * in all regions of the Nation." In March 2010, a unanimous Commission endorsed reform of universal service programs to "encourage targeted investment in broadband infrastructure and emphasize the importance of broadband to the future of these programs." Reforming universal service to encompass broadband is also a keystone of the National Broadband Plan. Our current universal service support programs, including our high-cost program and our low-income programs, address deployment and income-related adoption barriers for voice. The Plan recommends that the Commission provide high-cost and low-income support that ensures that all households have the ability to subscribe to a high-quality broadband connection that provides both broadband and voice services.

79. Two subsections of section 254 bear particularly on whether to forbear from this universal service provision. First, section 254(c) defines universal service as "an evolving level of *telecommunications service.*" By not forbearing from section 254(c), the Commission would retain clear authority to support the availability and adoption of broadband Internet connectivity service through reformed high-cost and low-income programs in the Universal Service Fund.

80. Second, section 254(d) requires *all* providers of telecommunications service to contribute to the Universal Service Fund on an equitable and nondiscriminatory basis. Should the Commission apply the mandatory contribution requirement to broadband Internet connectivity providers? If so, should we delay implementation of the contribution obligation, through temporary forbearance or other means, until the Commission adopts rules governing specifically how broadband Internet connectivity providers should calculate their contribution consistent with the requirement that all telecommunications carriers "contribute[] on an equitable and nondiscriminatory basis," possibly as part of comprehensive Universal Service Fund reform?

81. If commenters suggest that we should forbear from applying the support provisions of section 254 in the context of broadband Internet connectivity service, we ask them to provide alternative proposals to ensure universal availability of broadband Internet connectivity services, and to assess the legal sustainability of proposed alternatives. If commenters suggest that we forbear from (or delay) applying the mandatory contribution provisions of section 254, what would be the consequences for the Universal Service Fund? The Commission has statutory authority to assess any provider of interstate telecommunications if that would serve the public interest. Nothing in this Notice should be understood to limit the Commission's ability to exercise this authority during the pendency of this proceeding.

82. *Possible Exclusion from Forbearance: Section 222.* Section 222 of the Communications Act requires providers of telecommunications services to protect their customers' confidential information, as well as proprietary information of other telecommunications service providers and equipment manufacturers. As discussed above, the Commission has supported applying this provision in the broadband context. Section 222 would appear to provide the Commission clear authority to implement appropriate privacy requirements for broadband Internet connectivity. We question, however, whether it would be in the public interest to apply section 222 to broadband Internet connectivity service immediately. It might be more effective for the Commission to interpret the specific provisions of section 222, including the definition of "customer proprietary network information," in the broadband context before requiring broadband Internet connectivity providers to comply. Proceeding otherwise could cause confusion and disparity among broadband Internet connectivity providers, and confusion for consumers. Compliance with section 222 could also be more expensive if the provision took effect immediately, and we later adopted specific rules. On the other hand, most providers are already subject to privacy requirements, at least for other services they provide; their costs of immediate compliance with section 222 may not outweigh the benefit to consumers of quick assurance of their privacy while using broadband Internet connectivity services. In

addition, section 631 of the Communications Act requires cable operators to fulfill certain obligations with respect to consumer privacy for cable or "other service[s]" to which a consumer subscribes. The term "other service" includes "any wire or radio communications service provided using any of the facilities of the cable operator that are used in the provision of cable service." How should the obligations of sections 222 and 631 be reconciled for cable operators offering broadband Internet service? More broadly, we seek comment on the application of section 222 to any wired broadband Internet connectivity service that may be classified as a telecommunications service, and on whether the public interest would be served by permitting section 222 to apply in the absence of new implementing rules. The Commission has previously forborne temporarily from applying a statutory provision or regulation. In 1994, soon after Congress authorized the Commission to deregulate wireless services, the Commission forbore temporarily from requiring or permitting CMRS providers to file tariffs for interstate access service. And in 2005, the Commission temporarily forbore from carrier eligibility requirements for universal service support, to provide victims of Hurricane Katrina access to wireless phone service.

83. One aspect of retaining the information service classification for broadband Internet service (other than for the Internet connectivity telecommunications service that may be offered separately with broadband Internet service) is that it minimizes interference with the FTC's ability to enforce the Federal Trade Commission Act's prohibition of unfair, deceptive, or anticompetitive practices by broadband Internet service providers. Section 5(a)(1) of the FTC Act declares to be unlawful all "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce," but section 5(a)(2) of the FTC Act restricts the FTC's ability to enforce this prohibition with respect to common carrier activities. We seek comment on how the Commission might use its authority under section 222 to ensure privacy for users of Internet connectivity without significantly compromising the FTC's ability to address privacy issues involving broadband Internet services and applications.

84. *Possible Exclusion from Forbearance: Section 255.* Section 255 requires telecommunications service providers to make their services accessible to individuals with disabilities, unless not reasonably achievable. As discussed above, the Commission has repeatedly expressed its intent to apply this requirement in the broadband context.

85. We seek comment on the appropriateness of implementing section 255 to ensure that Americans with disabilities have access to broadband Internet connectivity services. As with section 222, might it be appropriate to apply section 255 only after a separate notice-and-comment proceeding that allows detailed consideration of disabilities-access issues in the broadband context? We seek comment on implementation questions and other issues related to the application of section 255.

86. *Scope of Forbearance Generally.* We believe that the six sections we have just discussed—sections 201, 202, 208, 222, 254, and 255—could compose a sufficient set of tools for effecting the established policy approach and implementing the Commission's goals for 21st Century communications. Are there others that should be added to this list? Some provisions of Title II relate directly or indirectly to the effective application and enforcement of the six provisions we have identified. Section 214, for example, deals primarily with "Extension of Lines" yet contains section 214(e), which provides the framework for determining which carriers are eligible to participate in universal service support programs. Similarly, section 251(a)(2) directs telecommunications carriers "not to install network features, functions, or capabilities that do not comply with the guidelines and standards established pursuant to section 255," and section 225 establishes the telecommunications relay services program. Is application of these or any other provisions of Title II required to allow effective implementation and enforcement of the six provisions identified above? If so, should the Commission exempt such provisions from forbearance for administrative reasons, if this third approach to classification is adopted?

87. Are there provisions of Title II from which we lack authority to forbear? Section 10(a) directs the Commission to forbear from applying regulations or provisions of the Communications Act to telecommunications carriers or services in those instances where the Commission determines that the particular provision is unnecessary to ensure that carrier "charges, practices, classifications, or regulations * * * are just and reasonable and are not unjustly or unreasonably discriminatory;" enforcement of such regulation is "not necessary for the protection of consumers;" and forbearance is consistent with the public interest. We ask whether section 10 provides authority to forbear from provisions of the statute that do not directly impose obligations on carriers. For example, section 224 provides the framework for the Commission's regulation of pole attachments, including the rates therefor. Does section 10 provide the Commission authority to forbear from section 224 insofar as it imposes rate-related obligations on the Commission and utilities that own poles, rather than on telecommunications carriers or telecommunications services?

88. Similarly, section 253 permits the Commission to preempt state regulations that prohibit the provision of telecommunications services. Does section 10 provide the Commission authority to forbear from section 253, which does not impose obligations on telecommunications carriers? If the Commission were to forbear from section 253, how would the Commission's general authority to preempt inconsistent state requirements be affected?

89. Congress created the Commission in part "for the purpose of the national defense, [and] for the purpose of promoting safety of life and property through the use of wire and radio communication." Would it be consistent with the Commission's mission with respect to promoting safety of life and property, and consumer protection generally, to forbear from the portions of section 214(a) that address discontinuance, reduction, or impairment of service? Would it be consistent with our mission to forbear from section 214(d), which allows the Commission to require a carrier "to provide itself with adequate facilities for the expeditious and efficient performance of its service"; or section 218, which permits the Commission to "inquire into the management of the business of all carriers subject to this Act"? Does section 10 provide authority to forbear from these provisions? Should the Commission exclude them from forbearance so it may proceed with, for example, cybersecurity or data gathering initiatives, or would authority under sections 201 and 202 (or other provisions) be sufficient? How would forbearance from these provisions affect the Commission's ability to promote adequate service to underserved communities?

90. Also with regard to our national defense and homeland security mission, we note that section 229 directs the Commission to implement the provisions of the Communications

Assistance for Law Enforcement Act (CALEA). CALEA is a separate statute that requires "telecommunications carriers" to meet certain assistance capability requirements in support of electronic surveillance. The Commission has previously found that CALEA's definition of "telecommunications carrier" is broader than the definition of "telecommunications carrier" in the Communications Act. All service providers that are "telecommunications carriers" under the Communications Act are also "telecommunications carriers" subject to CALEA, and some providers—including facilities-based broadband Internet access providers—are subject to CALEA even if they are not "telecommunications carriers" as defined in the Communications Act. Specifically, the Commission held in 2005 that "facilities-based providers of any type of broadband Internet access service, including but not limited to wireline, cable modem, satellite, wireless, fixed wireless, and broadband access via powerline are subject to CALEA." Thus, it appears that regardless of whether we maintain the current statutory classification for broadband Internet service or classify Internet connectivity (or some other service) as a telecommunications service, CALEA will continue to apply to these providers. We seek comment on this analysis. In addition, as we do with regard to the sections described just above, we seek comment on whether section 10 would provide authority to forbear from section 229, and on whether forbearance from application of section 229 would be consistent with the purposes for which CALEA was enacted and the public interest. Finally, we emphasize that section 10 does not provide the Commission authority to forbear from provisions of CALEA or any other statute other than the Communications Act.

91. Section 257(c) requires the Commission to make periodic reports to Congress concerning the elimination of previously identified barriers to market entry by entrepreneurs and other small businesses. This obligation applies to "the provision and ownership of telecommunications and information services" and thus applies regardless of the legal classification of broadband Internet service and broadband Internet connectivity service. It thus would appear that none of the three alternative approaches suggested here would affect the Commission's duty to make the mandated reports. Nor, given the importance of lowering barriers to market entry, do we contemplate any circumstance in which it would be sound policy to cease making the reports. We seek comment on these issues and on how best to ensure that the obligation of section 257(c) is preserved in this context.

92. We further seek comment on whether there are provisions of Title II that would require interpretation even after forbearance. For example, would forbearance from section 203 mean that carriers may not file tariffs even if they want to, or just that they are not required to do so? Would the Commission's review of transactions involving providers of broadband Internet connectivity service be affected if the Commission forbore from applying section 214?

93. We also seek comment on whether there are approaches superior or complementary to forbearance that the Commission should consider as means of easing regulatory burdens. For example, in the past the Commission has "streamlined" the statutory procedures that apply to non-dominant carriers, and has granted blanket authority to all carriers under section 214 to provide domestic interstate services and to construct, acquire, or operate any domestic transmission line. Is any similar approach appropriate here?

94. Finally, we seek comment on the role of third party standard setting bodies if the Commission were to adopt one of the deregulatory approaches described here.

Application of the Statutory Forbearance Criteria

95. *Charges, Practices, Classifications, and Regulations.* In 2002, when the Commission decided to classify cable modem service as an information service, only 12 percent of American adults had broadband at home. Now nearly two-thirds of American adults use broadband at home. In just the last two years, home broadband use has grown more than 25 percent. The quality and availability of broadband services continue to improve, with cable and telephone companies investing about $20 billion in wireline broadband capital expenditures in 2008 and about $18 billion in 2009. As described in the National Broadband Plan, "[t]op advertised speeds available from broadband providers have increased in the past few years. Additionally, typical advertised download speeds to which consumers subscribe have grown approximately 20% annually for the last 10 years."

96. Still, a number of reported incidents suggest there is a role for the Commission. Comcast's secret disruption of its customers' peer-to-peer communications, which the Commission determined to be unjustified, is one example. There have been recent reports involving: AT&T's alleged failure to deliver DSL service at the speeds promised; allegations that although RCN promised subscribers "fast and uncapped" broadband, it delayed or blocked peer-to-peer file transfers without users' knowledge or consent; and Windstream's redirection of subscribers who used the default search function in the Firefox web browser to a Windstream "landing page." Furthermore, legislative developments described above suggest that Congress is not satisfied with the pace of broadband deployment, adoption, and utilization.

97. We seek comment on whether, in light of the current charges, practices, classifications, and regulations of broadband Internet connectivity service providers, it would be consistent with section 10(a)(1) for the Commission to forbear from all provisions of Title II except the six identified provisions. If we found on the record developed in response to this Notice that the marketplace for broadband Internet connectivity services is operating sufficiently well with regard to competition and consumers' interests, then retaining only the authority in sections 201, 202, and 208; reforming universal service under section 254; and continuing to enforce the privacy and access provisions of sections 222 and 255 could be sufficient to address current and foreseeable future concerns.

98. *Protection of Consumers and the Public Interest.* Section 10(b) directs the Commission, in making its public interest analysis, to "consider whether forbearance from enforcing the provision or regulation will promote competitive market conditions." As discussed above, the goals of any action to classify broadband Internet connectivity as a telecommunications service would include preserving the Commission's ability to step in when necessary to protect consumers and fair competition, while generally refraining from regulation where possible. Further, the Commission has tools to promote competition for broadband Internet services that would be unaffected by the forbearance proposal discussed here. We seek comment on this element of the forbearance test.

Maintaining Forbearance Decisions

99. We seek comment on whether, if we forbore from applying those provisions of Title II that go beyond minimally intrusive Commission oversight, that decision would likely

endure. Section 10 allows the Commission to revisit a decision to forbear. Normally, to depart from a prior decision, an agency may simply acknowledge that it is doing so and provide a rational explanation for the change, which may or may not need to be more detailed than the explanation for the original decision. The agency "need not demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one." Section 10, though, requires the Commission to forbear if the statutory criteria are met. Thus, to reverse a forbearance decision, the Commission must find that at least one of the criteria is no longer met with regard to a particular statutory provision. That determination would be subject to judicial review, and the Supreme Court has stated that an agency must "provide a more detailed justification than what would suffice for a new policy created on a blank slate" in instances where, for example, "its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account." Reversal of forbearance also might be in arguable tension with section 706(a) of the 1996 Act, which directs the Commission to "encourage the deployment on a reasonable and timely basis of advanced telecommunications capability to all Americans * * * by utilizing, in a manner consistent with the public interest, convenience, and necessity, * * * regulatory forbearance." We seek comment on the Commission's authority to reverse a forbearance decision concerning broadband Internet connectivity service. We also seek comment on what provisions, if any, could appropriately be included in a forbearance order to establish a heightened standard for justifying future "unforbearance."

100. If the Commission were to elect the option of classifying Internet connectivity as a telecommunications service but forbearing from most of Title II, then a reviewing court could in theory uphold the classification determination but vacate the accompanying forbearance in whole or in part. In that situation, the Commission could maintain the classification of broadband Internet connectivity service as telecommunications service and allow the relevant provisions of Title II, which the court restored, to apply. We seek comment on any lawful mechanisms that (assuming adoption of the third classification option) could be utilized to address this theoretical situation, even if that means the Commission would not, in the post-litigation situation just described, ultimately maintain the classification of Internet connectivity as a telecommunications service.

Effective Dates

101. If the Commission decided to alter its current approach to Internet connectivity service, affected providers might need time to adjust to any new requirements. To reflect this, the Commission could delay the effective date of a classification (or classification and forbearance) decision for 180 days after release, or another suitable period. Moreover, as discussed above, certain provisions of Title II, such as sections 222, 254(d), and 255, could be phased-in on an even longer timetable. We seek comment on the effective date the Commission should adopt for a classification decision under one of the approaches proposed here, or an alternative approach identified by the commenter.

Terrestrial Wireless and Satellite Services

102. The Commission currently classifies broadband Internet service solely as an information service regardless of whether it is provided over cable facilities, wireline facilities, wireless facilities, or power lines. At the same time, the Commission has in the past taken a deliberate approach to extending its classification framework. In particular, though the Commission had classified all cable modem and wireline Internet access services as information services by 2005, it was not until 2007 that it extended that classification to wireless broadband Internet services, even though the first 3G networks went into service in 2003.

103. We seek comment on which of the three legal frameworks specifically discussed in this Notice, or what alternate framework, would best support the Commission's policy goals for wireless broadband. In addition, as the Commission recently noted in the *Open Internet NPRM,* "there are technological, structural, consumer usage, and historical differences between mobile wireless and wireline/cable networks." We seek comment on whether these differences are relevant to the Commission's statutory approach to terrestrial wireless and satellite-based broadband Internet services. Do consumers today view wireless broadband as a substitute for wired services? How are terrestrial wireless and satellite Internet services purchased, provided, and perceived?

104. Several provisions of Title III of the Communications Act provide the Commission authority to impose on spectrum licensees obligations that are in the public interest. For example, section 301 provides the Commission authority to regulate "radio communications" and "transmission of energy by radio." Under section 303, the Commission has the authority to establish operational obligations for licensees that further the goals and requirements of the Act if the obligations are in the "public convenience, interest, or necessity" and not inconsistent with other provisions of law. Section 303 also authorizes the Commission, subject to what the "public interest, convenience, or necessity requires," to "[p]rescribe the nature of the service to be rendered by each class of licensed stations and each station within any class." Section 307(a) likewise authorizes the issuance of licenses "if public convenience, interest, or necessity will be served thereby." Section 316 provides a similar test for new conditions on existing licenses, authorizing such modifications if "in the judgment of the Commission such action will promote the public interest, convenience, and necessity." On the other hand, Title III provides the Commission no express authority to extend universal service to wireless broadband Internet services. We seek comment on whether these or other technical, market, or legal considerations justify different classification of wireless and wired broadband Internet services. We also seek comment on whether our approach to classification of non-facilities-based Internet service providers should be different in the wireless context, or the same as in the wired context.

105. In addition, section 332 sets forth various provisions concerning the regulatory treatment of mobile wireless service. Sections 332(c)(1) and (c)(3), in particular, require that CMRS providers be regulated as common carriers under Title II of the Act. To what extent should section 332 of the Act affect our classification of wireless broadband Internet services? Section 332(c)(1) gives the Commission the authority to specify certain provisions of Title II as inapplicable to CMRS providers. If the Commission were to take the third way described above in the wireless broadband context, could it and should it apply section 332(c)(1) as well as section 10 in its forbearance analysis? We also seek comment on whether the Commission would have reason to apply sections 201 and 202 differently

to wireless and wired broadband Internet services.

106. We also ask commenters to address whether, if the Commission were to alter its present approach to broadband Internet service, it would be preferable for the Commission to address wireless services at the same time that it addresses wired services, or whether there are reasons for the Commission to defer a decision on classification of non-wired broadband Internet services (and any associated forbearance if a wireless broadband telecommunications service is identified).

Non-Facilities-Based Internet Service Providers

107. In 1998, the Commission addressed non-facilities-based Internet service providers and concluded that they provided only information services. In *Brand X,* Justice Scalia stated in his dissent that non-facilities-based Internet service providers using telephone lines to provide DSL service stand in a different position in the eyes of the consumer than the provider of the physical connection. Some industry members have suggested, however, that providers of Internet connectivity could avoid compliance with consumer protection measures by relying on non-facilities-based affiliates to offer retail broadband Internet service. We seek comment on what policy goals we should have for non-facilities-based Internet service providers, and what legal foundation for non-facilities-based Internet service providers can best support effective implementation of those goals.

Internet Backbone Services, Content Delivery Networks, and Other Services

108. The focus of this proceeding is limited to the classification of broadband Internet service. We remain cognizant that, under the Act, all information services are provided "via telecommunications," and therefore the use of telecommunications does not, on its own, warrant the identification of a separate telecommunications service component. For example, we do not intend to address in this proceeding the classification of information services such as e-mail hosting, web-based content and applications, voicemail, interactive menu services, video conferencing, cloud computing, or any other offering aside from broadband Internet service. Services that utilize telecommunications to afford access to particular stored content, such as content delivery networks, also are outside the scope of this proceeding. Nor do we intend here to address or disturb our treatment of services that are not sold by facilities-based Internet service providers to end users in the retail market, including, for example, Internet backbone connectivity arrangements. In short, the Commission proposes not to change its treatment of services that fall outside a commonsense definition of broadband Internet service. We seek comment on whether any of the three legal approaches described in this Notice would affect these services directly or indirectly, and how we should factor that into our decision-making about the treatment of broadband Internet service.

109. In a separate proceeding, the Commission has asked for public comment on the treatment of other services (including Internet-Protocol-based voice and subscription video services) that may be provided over the same facilities used to provide broadband Internet service to consumers, but that have not been classified by the Commission. The Commission has described these as "managed" or "specialized" services, and recognized "that these managed or specialized services may differ from broadband Internet services in ways that recommend a different policy approach, and it may be inappropriate to apply the rules proposed here to managed or specialized services." We do not intend to address the classification or treatment of these services in this proceeding. We seek comment on whether any of the three legal approaches identified in this Notice would affect these services directly or indirectly, and how we should factor that into our decision-making about the treatment of Internet connectivity service.

State and Local Regulation of Broadband Internet and Internet Connectivity Services

110. We also ask commenters to address the implications for state and local regulation that would arise from the three proposals described above. Under each of the three approaches, what would be the limits on the states' or localities' authority to impose requirements on broadband Internet service and broadband Internet connectivity service?

111. We anticipate that if a state were to impose requirements on broadband Internet connectivity service or broadband Internet service that are contrary to a Commission decision not to apply similar requirements, we would have authority under the Communications Act and the Supremacy Clause of the United States Constitution (Article III, section 2) to preempt those state requirements. In addition, section 10(e) provides that "[a] State commission may not continue to apply or enforce any provision of this Act that the Commission has determined to forbear from applying." We seek comment on the application of these provisions in the context of broadband Internet service and broadband Internet connectivity service, the states' role in the broadband marketplace, and how our decision to apply or not apply section 253 could relate to this authority.

Related Actions

112. We seek comment on whether there are actions we can and should take outside the proceeding this Notice initiates to implement the established policy approach to broadband Internet service. As one example, the Commission could decline to pursue the "open access" policies for cable modem service on which the Commission sought comment in 2002 when it decided to classify cable modem service as a single information service. We seek comment on terminating the docket initiated by the notice of proposed rulemaking that accompanied the *Cable Modem Declaratory Ruling,* and we invite additional proposals.

Procedural Matters

Paperwork Reduction Act

113. This document does not contain proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified "information collection burden for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 47 U.S.C. 3506(c)(4).

Ex Parte Presentations

114. The inquiry this Notice initiates shall be treated as a "permit-but-disclose" proceeding in accordance with the Commission's *ex parte* rules. Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentations must contain summaries of the substance of the presentations and not merely a listing of the subjects discussed. More than a one or two sentence description of the views and arguments presented generally is required. Other requirements pertaining to oral and written presentations are set forth in § 1.1206(b) of the Commission's rules.

Ordering Clause

115. Accordingly, *it is ordered* that, pursuant to the authority contained in sections 4(i), 4(j), 10, 218, 303(b), 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), 160, 218, 303(b), 303(r), and 403, this Notice of Inquiry *is adopted.*

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2010–15349 Filed 6–23–10; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 10:23 a.m. on Tuesday, June 22, 2010, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters related to the Corporation's supervision and resolution activities.

In calling the meeting, the Board determined, on motion of Director Thomas J. Curry (Appointive), seconded by Vice Chairman Martin J. Gruenberg, concurred in by Director John E. Bowman (Acting Director, Office of Thrift Supervision), Director John C. Dugan (Comptroller of the Currency), and Chairman Sheila C. Bair, that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Board Room of the FDIC Building located at 550–17th Street, NW., Washington, DC.

Dated: June 22, 2010.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2010–15496 Filed 6–22–10; 4:15 pm]

BILLING CODE P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS10–2]

Appraisal Subcommittee; Rules of Operation; Amendment

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of amendment to rules governing the Chairperson and Vice Chairperson of the Appraisal Subcommittee.

SUMMARY: The Appraisal Subcommittee (Subcommittee) of the Federal Financial Institutions Examination Council is amending the following sections:

Section 3.04 of the Rules of Operation, which sets forth the term of the Chairperson and designation of a person to act in the absence of the Chairperson, as amended will define the Chairperson's term to expire on March 31 every even-numbered year. The language to designate a person to act in the Chairperson's absence will be deleted due to the proposed amendment for selection of a Vice Chairperson. A subsection 3.04.a will be added which sets forth the selection process of the Vice Chairperson, and describes the Vice Chairperson's term and duties.

Section 3.06 of the Rules of Operation designates the Vice Chairperson to preside over Subcommittee meetings in the Chairperson's absence.

DATES: *Effective Date:* Immediately.

FOR FURTHER INFORMATION CONTACT: James R. Park, Executive Director, at (202) 595–7575, or Alice M. Ritter, General Counsel, at (202) 595–7577, via Internet e-mail at *jim@asc.gov* and *alice@asc.gov,* respectively, or by U.S. Mail at Appraisal Subcommittee, 1401 H Street, NW., Suite 760, Washington, DC 20005.

SUPPLEMENTARY INFORMATION: The Subcommittee, on May 29, 1991, adopted Rules of Operation, which were published at 56 FR 28561 (June 21, 1991). The Rules of Operation describe, among other things, the organization of Subcommittee meetings, notice requirements for meetings, quorum requirements and certain practices regarding the disclosure of information. The Subcommittee approved by notation vote on May 5, 2010, substantive revisions to Sections 3.04 and 3.06 of the Rules of Operation to address the appointment of a Vice Chairperson for the Subcommittee.

The Subcommittee is publishing new Sections 3.04, 3.04.a and 3.06 to conform with 5 U.S.C. 552(a)(1)(C), which requires the publication of agency rules of operation in the **Federal Register**. The notice and publication requirements of 5 U.S.C. 553 do not apply to the adoption of Sections 3.04 and 3.06 because it is a "rule of agency organization, procedure, or practice" exempt from the public notice and comment process under 5 U.S.C. 553(b)(3)(A).

Based on the foregoing, the Subcommittee adopts new Sections 3.04, 3.04.a and 3.06 of the Rules of Operation, as follows, effective immediately:

Rules of Operation

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Article III Members of the Subcommittee

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Section 3.04. *Chairperson of the Subcommittee.* The Council shall elect a Chairperson of the Subcommittee. The term of office of the Chairperson shall be for a two-year term. Section 1104(a)(12 U.S.C. 3333(a)). The Chairperson's term shall expire on March 31 every even-numbered year. The Chairperson shall carry out all duties required by the Act and these Rules and shall perform such other duties as from time to time may be assigned by the Subcommittee

Section 3.04.a. *Vice Chairperson of the Subcommittee.* The outgoing Chairperson shall serve as the Vice Chairperson for a period of one year, with the term ending March 31. During the March meeting, the Subcommittee shall vote upon a Vice Chairperson to serve for the next one-year term, which shall coincide with the second year of the Chairperson's two-year term. It is anticipated that the Vice Chairperson could serve as the next Chairperson, if so elected by the Council. The Vice Chairperson shall assist the Chairperson as needed, and shall act on behalf of the Subcommittee in the absence or incapacity of the Chairperson.

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Section 3.06. *Organization of Subcommittee Meetings.*

(a) The Chairperson of the Subcommittee shall preside at Subcommittee meetings. In his or her absence, the Vice Chairperson shall preside at such Subcommittee meeting.

(b) The Secretary, or in the absence of the Secretary, any person designated by the Chairperson, shall draft and transmit the minutes of the meeting to each member. The Executive Director is appointed to serve as Secretary, and shall be responsible for recording the minutes, including the full text of each resolution voted on by the Subcommittee and the substance of each action voted on by the Subcommittee as

well as the vote. The Secretary will also be responsible for certifying or attesting to true copies, minutes, or other documents stating that actions were in fact taken by the Subcommittee. The Secretary will also be responsible for maintaining and preserving at a single place, available for inspection at reasonable times by any member of the Subcommittee or any person designated by any member, the complete minutes of the proceedings of the Subcommittee. The Executive Director may delegate the ministerial duties of Secretary to Subcommittee staff.

(c) Regular meetings of the Subcommittee shall be held in Washington, DC, at a location designated by the Chairperson, or in such other place as the Subcommittee may designate. Special meetings shall be held in such place and at such location as designated by the calling party or parties.

(d) Regular meetings of the Subcommittee shall be held at least monthly at the call of the Chairperson. Special meetings shall be held as provided in section 3.07(b) below.

* * * * *

By the Appraisal Subcommittee, June 16, 2010.

Deborah S. Merkle,

Chairman.

[FR Doc. 2010–15320 Filed 6–23–10; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than July 9, 2010.

A. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. Richard Earl Williams, Jr., Cameron, Texas, individually and as Trustee of the Richard E. Williams Exempt Trust; Debora Evans, Belton, Texas, individually and as Trustee of the Debora Evans Exempt Trust; Richard Earl Williams, Jr. and Debora Evans as co–Trustees of (i) the Williams Family Exempt Trust, (ii) the Victoria Grace Williams Special Trust, (iii) the Thomas Joseph Evans 2002 Trust and (iv) the Elizabeth Ashton Williams 2002 Trust, all of Cameron, Texas; and Richard E. Williams, Jr., Debora Evans and the above named trusts, collectively (the "Williams Family Group"), to retain voting shares of Cameron Financial Corporation and thereby indirectly retain voting shares of Classic Bank, N.A., both of Cameron, Texas.

Board of Governors of the Federal Reserve System, June 21, 2010.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2010–15283 Filed 6–23–10; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 19, 2010.

A. Federal Reserve Bank of Cleveland (Nadine Wallman, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101–2566:

1. Standard Financial Corp., Murrysville, Pennsylvania; to become a bank holding company by acquiring 100 percent of the voting shares of Standard Bank, PaSB, Murrysville, Pennsylvania.

Board of Governors of the Federal Reserve System, June 21, 2010.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2010–15284 Filed 6–23–10; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

[OP–1385]

Payment System Risk Policy; Daylight Overdraft Posting Rules

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Announcement.

SUMMARY: As part of its Payment System Risk Policy, the Board is announcing posting rules for a new same-day automated clearing house (ACH) service. The Reserve Banks' FedACH SameDay service, which will include certain debit transactions, will be available only to customers who elect to participate.

DATES: *Effective Date:* August 2, 2010.

FOR FURTHER INFORMATION CONTACT: Susan Foley, Deputy Associate Director (202–452–3596), Holly Kirkpatrick, Senior Financial Services Analyst, Payment System Risk (202–452–2796), or Jennifer Davidson, Senior Financial Services Analyst, Retail Payments (202–452–2446), Division of Reserve Bank Operations and Payment Systems, Board of Governors of the Federal Reserve System; for users of Telecommunications Device for the Deaf ("TDD") only, contact (202) 263–4869.

SUPPLEMENTARY INFORMATION:

I. Background

The Reserve Banks will be offering an opt-in, same-day settlement service for certain ACH debit payments through the FedACH service effective August 2, 2010.[1] FedACH customers may opt-in to

[1] For additional information on the FedACH SameDay service, please contact your Federal Reserve Account Executive or visit *http://www.frbservices.org.*

this service by completing a participation agreement. As part of the agreement, depository institutions may choose the extent of their participation: They may send only, receive only, or send and receive same-day debit items. This service will be limited to transactions arising from consumer checks converted to ACH and consumer debit transfers initiated over the Internet and phone.[2]

Institutions that choose to use this service should be aware of the posting times and associated settlement times established for same-day forward and return transfers, as these times could influence how participating institutions manage their Federal Reserve accounts, especially late in the day.[3] When the Reserve Banks offer new financial services, the Board determines when the payments will post to an institution's Federal Reserve account so it may manage and appropriately fund its account.[4] The following table outlines the transmission deadlines and associated posting times for the FedACH SameDay service.[5]

FedACH SameDay opt-in service	Transmission deadline to FedACH	Posting time
Forward same-day debit transfers	2 p.m	5 p.m.
Return same-day debit transfers	4:30 p.m	5:30 p.m.

In considering these transmission deadlines and posting times, the Board sought to provide receiving institutions with enough time to process same-day transactions. Depository institutions may send a same-day forward item to FedACH until 2 p.m. FedACH will process these forward items and send them to the receiving institutions by approximately 4 p.m., and these items will settle the same day at 5 p.m. The Board also wanted to ensure that institutions have sufficient time to manage their Federal Reserve account if they receive a returned debit transfer late in the day. Depository institutions will have until 4:30 p.m. to return same-day debit items for same-day settlement.[6] FedACH will process and send the returned items to the originating institutions by approximately 5 p.m., and these items will settle the same day at 5:30 p.m. The Board believes that because these processing and posting times provide institutions with information sufficiently in advance of the close of Fedwire, participants in the FedACH SameDay service will be able to react appropriately to any debit transfers they may receive in their Federal Reserve accounts.

The Board also considered the possibility of how extensions to the FedACH service may affect the FedACH SameDay service. Today, under certain circumstances, FedACH customers may request an extension to the transmission deadline of 2 p.m. for immediate-settlement transactions. Immediate-settlement transactions include ACH return items and check-truncation items. The posting time for these items is 5 p.m. While customers will not be able to request an extension to the FedACH SameDay service, the transmission deadline for this service may be minimally affected by extensions granted for the immediate-settlement transactions. If a customer is granted an extension, FedACH would extend both the transmission deadline to send immediate-settlement return payments and the transmission deadline to send same-day forward items past 2 p.m. While this extension would grant all FedACH customers more time to send these items, it would not delay the posting times as FedACH would absorb the extension by shortening its processing window. Depository institutions interested in learning more detailed information about the FedACH SameDay service should contact their local Reserve Bank or visit *http://www.frbservices.org.*

II. Competitive Impact Analysis

The Board conducts a competitive impact analysis when it considers a change, such as introducing posting rules for a new service. Specifically, the Board determines whether there would be a direct and material adverse effect on the ability of other service providers to compete with the Federal Reserve due to differing legal powers or due to the Federal Reserve's dominant market position deriving from such legal differences.[7] The Board believes that there are no adverse effects to other service providers resulting from the new posting rules. While FedACH is the only ACH operator that is currently offering a same-day service, if the other ACH operator elects to offer a same-day service, FedACH would support inter-operator transfers to enable customers to benefit from both operators' same-day service offerings.

III. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506; 5 CFR 1320 Appendix A.1), the Board reviewed the new posting rules under the authority delegated to the Board by the Office of Management and Budget. No collections of information pursuant to the Paperwork Reduction Act are contained in these new posting rules.

IV. Federal Reserve Policy on Payment System Risk

The Federal Reserve Policy on Payment System Risk, Section II.A. under the subheading "Procedures for Measuring Daylight Overdrafts," is amended with changes as follows in *italics.*

Procedures for Measuring Daylight Overdrafts[8]

Post at 5 p.m. Eastern Time:

+/− *FedACH SameDay service transactions.*

+ Treasury checks, postal money orders, and EZ–Clear savings bond redemptions in separately sorted

[2] This service is limited to the origination of non-government debit payments and includes only Accounts Receivable Entry (ARC), Back Office Conversion Entry (BOC), Point-of-Purchase Entry (POP), Telephone-Initiated Entry (TEL), Represented Check Entry (RCK), and Internet-Initiated Entry (WEB).

[3] The posting time is the time by which a transaction will be recorded for daylight overdraft purposes and reflected in an institution's daylight overdraft balance. Settlement for the transaction will occur approximately fifteen to thirty minutes before the associated posting time and will be reflected in the institution's account balance. Institutions may view their real-time account balance and daylight overdraft balance in Account Management Information (AMI), which is a service offered by the Reserve Banks.

[4] Under the current posting times, government and commercial ACH credit transactions post at 8:30 a.m. Eastern Time and debit transactions post at 11 a.m. Eastern Time. ACH return transactions post at 5 p.m. Eastern Time.

[5] All times associated with the deadlines and posting rules are Eastern Time.

[6] Institutions have the option of returning same-day items by 4:30 p.m. for same-day return settlement at 5:30 p.m. If a same-day item is not returned by the same-day return deadline, institutions have until the generally applicable return deadline specified in the National Automated Clearing House Association (NACHA) rules to return items.

[7] Federal Reserve Regulatory Service, 7–145.2.

[8] These posting times do not affect the overdraft restrictions and overdraft-measurement provisions for nonbank banks established by the Competitive Equality Banking Act of 1987 and the Board's Regulation Y (12 CFR 225.52).

deposits; these items must be deposited by 4 p.m. Eastern Time.

+ Local Federal Reserve Bank checks; these items must be presented before 3:00 p.m. Eastern Time.

+/− *Immediate-settlement* ACH transactions; these transactions include ACH return items and check-truncation items.

Post at 5:30 p.m. Eastern Time:

+/− *FedACH SameDay service return transactions.*

By order of the Board of Governors of the Federal Reserve System, acting through the Director of the Division of Reserve Bank Operations and Payment Systems under delegated authority, June 16, 2010.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 2010–15276 Filed 6–23–10; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

Notice of Availability of the Draft Environmental Impact Statement for Improvements to the Calexico West Port of Entry, Calexico, CA

AGENCY: Public Buildings Service, GSA.

ACTION: Notice of Availability and public hearing for the Draft Environmental Impact Statement.

SUMMARY: The General Services Administration (GSA) announces the availability of the Draft Environmental Impact Statement (EIS) for Improvements to the Calexico West Port of Entry, Calexico, California, for public review and comment. The EIS provides GSA and its stakeholders an analysis of the environmental impacts resulting from ongoing operations as well as reasonable alternatives for renovation, replacement, and continued operation of the Calexico West Port of Entry, located in south-central California.

DATES: Comments on the Draft Environmental Impact Statement may be submitted during the public comment period, which will commence with the U.S. Environmental Protection Agency's publication of the **Federal Register** Notice of Availability for this document and end on August 18, 2010. Comments may be submitted in writing, orally, or by electronic mail to the General Services Administration at the address, phone number, or e-mail listed below. Oral or written comments may also be submitted at public meetings to be held on June 22 and July 14, 2010, between 3 and 7 p.m., at the Calexico City Hall, 608 Heber Avenue, Calexico, California. Comments submitted will be considered in preparation of the Final Environmental Impact Statement.

FOR FURTHER INFORMATION CONTACT: Mr. Greg Smith, GSA Regional Environmental Quality Advisor, Portfolio Management Division, Capital Investment Branch (9P2PTC), U.S. General Services Administration, 880 Front Street, Room 4236, San Diego, California 92101, (619) 557–6169 or via e-mail to *greg.smith@gsa.gov.* Oral and written comments may also be submitted at the public hearing described in the **DATES** section. Requests for copies of the Draft Calexico West Port of Entry EIS or other matters regarding this environmental review should be referred to Greg Smith at the address above.

SUPPLEMENTARY INFORMATION: A notice of availability will be mailed to all agencies, organizations, and individuals who participated in the scoping process or were identified during the EIS process. GSA has distributed copies of the Draft Calexico West Port of Entry EIS to appropriate Congressional members and committees, the state of California, American Indian tribal governments, local county governments, other Federal agencies, and other interested parties who have already requested copies.

The Draft EIS was prepared pursuant to the National Environmental Policy Act of 1969 (NEPA) [42 U.S.C. 4321 *et seq.*] and the Council on Environmental Quality NEPA regulations [40 CFR part 1500]. GSA proposes to continue operating the Calexico West Port of Entry, which is located in Calexico in south-central California. GSA has identified and assessed several design options for the renovation, replacement, and continued operation of the Calexico West Port of Entry. In addition, GSA analyzed the No Action Alternative in which GSA would continue the status quo, that is, operate the port of entry in its current configuration, with only minor planned upgrades.

The Draft Calexico Port of Entry EIS identifies the expected environmental impacts from facility operations for each alternative. For each alternative, impact discussions are presented by resource area (*e.g.,* land use, geology and soils) or topic area (*e.g.,* traffic, environmental justice).

After the public comment period, which ends August 18, 2010, GSA will consider the comments received, revise the Draft EIS, select a preferred alternative, and issue a Final EIS. GSA will consider the Final EIS, along with other economic and technical considerations, to make a decision on the appropriate course for improvements at the Calexico West Port of Entry.

ADDRESSES: Comments may be submitted in writing to: Mr. Greg Smith, Regional Environmental Quality Advisor, Portfolio Management Division, Capital Investment Branch (9P2PTC), U.S. General Services Administration, 880 Front Street, Room 4236, San Diego, California 92101, or via e-mail to *greg.smith@gsa.gov.* Oral and written comments may also be submitted at the public meetings described in the **DATES** section. Copies of the Draft Calexico Environmental Impact Statement may be downloaded from *http://www.gsa.gov/nepalibrary.* Other matters regarding this environmental review should be referred to Greg Smith at the address above.

Dated: *June 10, 2010.*

Samuel R. Mazzola,

Director, Portfolio Management Division, Public Building Service, Pacific Rim Region.

[FR Doc. 2010–15299 Filed 6–23–10; 8:45 am]

BILLING CODE 6820–YF–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0181]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 26, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0298. Also include the FDA docket number found

in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Threshold of Regulation for Substances Used in Food-Contact Articles—(OMB Control Number 0910–0298)—Extension

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless one of the following is applicable: (1) It conforms to an exemption for investigational use under section 409(j), (2) it conforms to the terms of a regulation prescribing its use, or (3) in the case of a food additive that meets the definition of a food-contact substance in section 409(h)(6), there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) or an effective notification in accordance with section 409(a)(3)(B).

The regulations in § 170.39 (21 CFR 170.39) established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation or an effective notification. The agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 part per billion (ppb). The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

In order to determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes the following components: (1) The chemical composition of the substance for which the request is made, (2) detailed information on the conditions of use of the substance, (3) a clear statement of the basis for the request for exemption from regulation as a food additive, (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance, (5) results of a literature search for toxicological data on the substance and its impurities, and (6) information on the environmental impact that would result from the proposed use.

FDA uses this information to determine whether the food-contact article meets the threshold criteria. Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves.

In the **Federal Register** of April 9, 2010 (75 FR 18209), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.39	7	1	7	48	336

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In compiling these estimates, FDA consulted its records of the number of regulation exemption requests received in the past 3 years. The annual hours per response reporting estimate of 48 hours is based on information received from representatives of the food packaging and processing industries and agency records.

FDA estimates that approximately 7 requests per year will be submitted under the threshold of regulation exemption process of § 170.39, for a total of 336 hours. The threshold of regulation process offers one advantage over the premarket notification process for food-contact substances established by section 409(h) of the act (OMB control number 0910–0495) in that the use of a substance exempted by the agency is not limited to only the manufacturer or supplier who submitted the request for an exemption. Other manufacturers or suppliers may use exempted substances in food-contact articles as long as the conditions of use (e.g., use levels, temperature, type of food contacted, etc.) are those for which the exemption was issued. As a result, the overall burden on both the agency and the regulated industry would be significantly less in that other manufacturers and suppliers would not have to prepare, and FDA would not have to review, similar submissions for identical components of food-contact articles used under identical conditions. Manufacturers and other interested persons can easily access an up-to-date list of exempted substances which is on display at FDA's Division of Dockets Management and on the Internet at *http://www.cfsan.fda.gov*. Having the list of exempted substances publicly available decreases the likelihood that a company would submit a food additive petition or a notification for the same type of food-contact application of a substance for which the agency has previously granted an exemption from the food additive listing regulation requirement.

Dated: June 16, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–15302 Filed 6–23–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0273]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices: Current Good Manufacturing Practice Quality System Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain

information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on recordkeeping requirements related to the medical devices current good manufacturing practice (CGMP) quality system (QS) regulation (CGMP/QS regulation).

DATES: Submit either electronic or written comments on the collection of information by August 23, 2010.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20857, 301–796–5156 email: *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices: Current Good Manufacturing Practice Quality System Regulations—21 CFR Part 820 (OMB Control Number 0910–0073)—Extension

Under section 520(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(f)), the Secretary of the Department of Health and Human Services has the authority to prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety and effectiveness of a device), packing, storage, and installation of a device conform to CGMP, as described in such regulations, to assure that the device will be safe and effective and otherwise in compliance with the act.

The CGMP/QS regulation implementing authority provided by this statutory provision is found under part 820 (21 CFR part 820) and sets forth basic CGMP requirements governing the design, manufacture, packing, labeling, storage, installation, and servicing of all finished medical devices intended for human use. The authority for this regulation is covered under sections 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, and 803 of the act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, and 383). The CGMP/QS regulation includes requirements for purchasing and service controls, clarifies recordkeeping requirements for device failure and complaint investigations, clarifies requirements for verifying/validating production processes and process or product changes, and clarifies requirements for product acceptance activities quality data evaluations and corrections of nonconforming product/quality problems.

Requirements are compatible with specifications in the international standards "ISO 9001: Quality Systems Model for Quality Assurance in Design/Development, Production, Installation, and Servicing." The CGMP/QS information collections will assist FDA inspections of manufacturers for compliance with QS requirements encompassing design, production, installation, and servicing processes.

Section 820.20(a) through (e) requires management with executive responsibility to establish, maintain, and/or review the following topics: (1) The quality policy, (2) the organizational structure, (3) the quality plan, and (4) the quality system procedures of the organization.

Section 820.22 requires the conduct and documentation of QS audits and reaudits.

Section 820.25(b) requires the establishment of procedures to identify training needs and documentation of such training.

Section 820.30(a)(1) and (b) through (j), requires in respective order, the establishment, maintenance, and/or documentation of the following topics: (1) Procedures to control design of class III and class II devices and certain class I devices as listed therein; (2) plans for design and development activities and updates; (3) procedures identifying, documenting, and approving design input requirements; (4) procedures defining design output, including acceptance criteria, and documentation of approved records; (5) procedures for formal review of design results and documentation of results in the design history file (DHF); (6) procedures for verifying device design and documentation of results and approvals in the DHF; (7) procedures for validating device design, including documentation of results in the DHF; (8) procedures for translating device design into production specifications; (9) procedures for documenting, verifying, and validating approved design changes before implementation of changes; and (10) the records and references constituting the DHF for each type of device.

Section 820.40 requires manufacturers to establish and maintain procedures controlling approval and distribution of required documents and document changes.

Section 820.40(a) and (b) requires the establishment and maintenance of procedures for the review, approval, issuance, and documentation of required records (documents) and changes to those records.

Section 820.50(a)(1), (a)(2), (a)(3), and (b) requires the establishment and maintenance of procedures and requirements to ensure service and product quality, records of acceptable suppliers, and purchasing data

describing specified requirements for products and services.

Sections 820.60 and 820.65 require, respectively, the establishment and maintenance of procedures for identifying all products from receipt to distribution and for using control numbers to track surgical implants and life-sustaining or supporting devices and their components.

Section 820.70(a)(1) through (a)(5), (b) through (e), (g)(1) through (g)(3), (h), and (i) requires the establishment, maintenance, and/or documentation of the following topics: (1) Process control procedures; (2) procedures for verifying or validating changes to specification, method, process, or procedure; (3) procedures to control environmental conditions and inspection result records; (4) requirements for personnel hygiene; (5) procedures for preventing contamination of equipment and products; (6) equipment adjustment, cleaning, and maintenance schedules; (7) equipment inspection records; (8) equipment tolerance postings, procedures for utilizing manufacturing materials expected to have an adverse effect on product quality; and (9) validation protocols and validation records for computer software and software changes.

Sections 820.72(a), (b)(1), and (b)(2) and 820.75(a) through (c) require, respectively, the establishment, maintenance, and/or documentation of the following topics: (1) Equipment calibration and inspection procedures; (2) national, international or in-house calibration standards; (3) records that identify calibrated equipment and next calibration dates; (4) validation procedures and validation results for processes not verifiable by inspections and tests; (5) procedures for keeping validated processes within specified limits; (6) records for monitoring and controlling validated processes; and (7) records of the results of revalidation where necessitated by process changes or deviations.

Sections 820.80(a) through (e) and 820.86, respectively, require the establishment, maintenance, and/or documentation of the following topics: (1) Procedures for incoming acceptance by inspection, test, or other verification; (2) procedures for ensuring that in-process products meet specified requirements and the control of product until inspection and tests are completed; (3) procedures for, and records that show, incoming acceptance or rejection is conducted by inspections, tests or other verifications; (4) procedures for, and records that show, finished devices meet acceptance criteria and are not distributed until device master record (DMR) activities are completed; (5) records in the device history record (DHR) showing acceptance dates, results, and equipment used; and (6) the acceptance/rejection identification of products from receipt to installation and servicing.

Sections 820.90(a), (b)(1), and (b)(2) and 820.100 require, respectively, the establishment, maintenance and/or documentation of the following topics: (1) Procedures for identifying, recording, evaluating, and disposing of nonconforming product; (2) procedures for reviewing and recording concessions made for, and disposition of, nonconforming product; (3) procedures for reworking products, evaluating possible adverse rework effect and recording results in the DHR; (4) procedures and requirements for corrective and preventive actions, including analysis, investigation, identification and review of data, records, causes, and results; and (5) records for all corrective and preventive action activities.

Section 820.100(a)(1) through (a)(7) states that procedures and requirements shall be established and maintained for corrective/preventive actions, including the following: (1) Analysis of data from process, work, quality, servicing records; investigation of nonconformance causes; (2) identification of corrections and their effectiveness; (3) recording of changes made; and (4) appropriate distribution and managerial review of corrective and preventive action information.

Section 820.120 states that manufacturers shall establish/maintain procedures to control labeling storage/application; and examination/release for storage and use, and document those procedures.

Sections 820.120(b) and (d), 820.130, 820.140, 820.150(a) and (b), 820.160(a) and (b), and 820.170(a) and (b), respectively, require the establishment, maintenance, and/or documentation of following topics: (1) Procedures for controlling and recording the storage, examination, release, and use of labeling; (2) the filing of labels/labeling used in the DHR; (3) procedures for controlling product storage areas and receipt/dispatch authorizations; (4) procedures controlling the release of products for distribution; (5) distribution records that identify consignee, product, date, and control numbers; and (6) instructions, inspection and test procedures that are made available, and the recording of results for devices requiring installation.

Sections 820.180(b) and (c), 820.181(a) through (e), 820.184(a) through (f), and 820.186 require, respectively, the maintenance of records that are: (1) Retained at prescribed site(s), made readily available and accessible to FDA and retained for the device's life expectancy or for 2 years; (2) contained or referenced in a DMR consisting of device, process, quality assurance, packaging and labeling, and installation, maintenance, and servicing specifications and procedures; (3) contained in a DHR and demonstrate the manufacture of each unit, lot, or batch of product in conformance with DMR and regulatory requirements, include manufacturing and distribution dates, quantities, acceptance documents, labels and labeling, control numbers; and (4) contained in a quality system record (QSR), consisting of references, documents, procedures, and activities not specific to particular devices.

Sections 820.198(a) through (c) and 820.200(a) through (d), respectively, require the establishment, maintenance, and/or documentation of the following topics: (1) Complaint files and procedures for receiving, reviewing and evaluating complaints; (2) complaint investigation records identifying the device, complainant, and relationship of the device to the incident; (3) complaint records that are reasonably accessible to the manufacturing site or at prescribed sites; (4) procedures for performing and verifying that device servicing requirements are met and that service reports involving complaints are processed as complaints; and (5) service reports that record the device, service activity, and test and inspection data.

Section 820.250 requires the establishment and maintenance of procedures to identify valid statistical techniques necessary to verify process and product acceptability; and sampling plans, when used, which are written and based on valid statistical rationale; and procedures for ensuring adequate sampling methods. The CGMP/QS regulation amends and revises the CGMP requirements for medical devices set out under part 820. The regulation adds design and purchasing controls; modifies previous critical device requirements; revises previous validation and other requirements; and harmonizes device CGMP requirements with QS specifications in the international standard "ISO 9001: Quality Systems Model for Quality Assurance in Design/Development, Production, Installation, and Servicing." The rule does not apply to manufacturers of components or parts of finished devices, nor to manufacturers of human blood and blood components subject to 21 CFR part 606. With respect to devices classified in class I, design control requirements apply only to class

I devices listed in § 820.30(a)(2) of the regulation. The rule imposes burden upon: (1) Finished device manufacturer firms, which are subject to all recordkeeping requirements; (2) finished device contract manufacturers, specification developers; and (3) repacker, relabelers, and contract sterilizer firms, which are subject only to requirements applicable to their activities. In addition, remanufacturers of hospital single-use devices (SUDs) will now be considered to have the same requirements as manufacturers in regard to this regulation. The establishment, maintenance and/or documentation of procedures, records, and data required by this regulation will assist FDA in determining whether firms are in compliance with CGMP requirements, which are intended to ensure that devices meet their design, production, labeling, installation, and servicing specifications and, thus are safe, effective and suitable for their intended purpose. In particular, compliance with CGMP design control requirements should decrease the number of design-related device failures that have resulted in deaths and serious injuries.

The CGMP/QS regulation applies to approximately 8,924 respondents. These recordkeepers consist of 8,945 original respondents and an estimated 18 hospitals that remanufacture or reuse SUDs. They include manufacturers, subject to all requirements and contract manufacturers, specification developers, repackers, relabelers, and contract sterilizers, subject only to requirements applicable to their activities. Hospital remanufacturers of SUDs are now defined to be manufacturers under guidelines issued by FDA's Center for Devices and Radiological Health (CDRH), Office of Surveillance and Biometrics. Respondents to this collection have no reporting activities, but must make required records available for review or copying during FDA inspection. The regulation contains additional recordkeeping requirements in such areas as design control, purchasing, installation, and information relating to the remanufacture of SUDs. The estimates for this burden are derived from those incremental tasks that were determined when the new CGMP/QS regulation became final as well as those carryover requirements. The carryover requirements are based on decisions made by the agency on July 16, 1992, under OMB Control Number 0910–0073, which still provides valid base line data.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Operating and Maintenance Costs	Total Hours
820.20(a)	8,924	1	8,924	7		62,468
820.20(b)	8,924	1	8,924	4		35,696
820.20(c)	8,924	1	8,924	6		53,544
820.20(d)	8,924	1	8,924	10		89,240
820.20(e)	8,924	1	8,924	10		89,240
820.22	8,924	1	8,924	33		294,492
820.25(b)	8,924	1	8,924	13		116,012
820.30(a)(1)	8,924	1	8,924	2		17,848
820.30(b)	8,924	1	8,924	6		53,544
820.30(c)	8,924	1	8,924	2		17,848
820.30(d)	8,924	1	8,924	2		17,848
820.30(e)	8,924	1	8,924	23		205,252
820.30(f)	8,924	1	8,924	37		330,188
820.30(g)	8,924	1	8,924	37		330,188
820.30(h)	8,924	1	8,924	3		26,772
820.30(i)	8,924	1	8,924	17		151,708
820.30(j)	8,924	1	8,924	3		26,772
820.40	8,924	1	8,924	9		80,316
820.40(a) and (b)	8,924	1	8,924	2		17,848
820.50(a)(1) through (a)(3)	8,924	1	8,924	22	1,300,805	196,328
820.50(b)	8,924	1	8,924	6		53,544

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Operating and Maintenance Costs	Total Hours
820.6	8,924	1	8,924	1		8,924
820.65	8,924	1	8,924	1		8,924
820.70(a)(1) through (a)(5)	8,924	1	8,924	2		17,848
820.70(b) and (c)	8,924	1	8,924	2		17,848
820.70(d)	8,924	1	8,924	3		26,772
820.70(e)	8,924	1	8,924	2		17,848
820.70(g)(1) through (g)(3)	8,924	1	8,924	1		8,924
820.70(h)	8,924	1	8,924	2		17,848
820.70(i)	8,924	1	8,924	8		71,392
820.72(a)	8,924	1	8,924	5		44,620
820.72(b)(1) and (b)(2)	8,924	1	8,924	1		8,924
820.75(a)	8,924	1	8,924	3		26,772
820.75(b)	8,924	1	8,924	1		8,924
820.75(c)	8,924	1	8,924	1		8,924
820.80(a) through (e)	8,924	1	8,924	5		44,620
820.86	8,924	1	8,924	1		8,924
820.90(a)	8,924	1	8,924	5		44,620
820.90(b)(1) and (b)(2)	8,924	1	8,924	5		44,620
820.100(a)(1) through (a)(7)	8,924	1	8,924	12		107,088
820.100(b)	8,924	1	8,924	1		8,924
820.120(b)	8,924	1	8,924	1		8,924
820.120(d)	8,924	1	8,924	1		8,924
820.130	8,924	1	8,924	1		8,924
820.140	8,924	1	8,924	6		53,544
820.150(a) and (b)	8,924	1	8,924	6		53,544
820.160(a) and (b)	8,924	1	8,924	1		8,924
820.170(a) and (b)	8,924	1	8,924	2		17,848
820.180(b) and (c)	8,924	1	8,924	2		17,848
820.181(a) through (e)	8,924	1	8,924	1		8,924
820.184(a) through (f)	8,924	1	8,924	1		8,924
820.186	8,924	1	8,924	1		8,924

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Operating and Maintenance Costs	Total Hours
820.198(a) through (c)	8,924	1	8,924	5		44,620
820.200(a) and (d)	8,924	1	8,924	3		26,772
820.25	8,924	1	8,924	1		8,924
Total					1,300,805	3,105,552

[1] There are no capital costs associated with this collection of information.

Explanation of Recordkeeping Burden Estimate

FDA estimates respondents will have a total annual recordkeeping burden of approximately 3,105,552 hours. This figure also consists of approximately 143,052 hours spent on a startup basis by 734 new firms.

Burden (labor) hour and cost estimates were originally developed under FDA contract by Eastern Research Group, Inc. (ERG) in 1996 when the CGMP/QS regulation became final. Additional factors considered in deriving estimates included the following:

- Establishment type: Query has been made of CDRH's registration/listing data bank and the current count was 7,748 domestic firms subject to CGMPs. It was also calculated that each year, the number of new domestic firms subject to CGMPs is 734. The average amount of firms therefore subject to CGMPs over the 3 years is therefore 8,924 and this figure has been used to calculate the total burden. Because the total number of registered firms is not static, the number of respondents will fluctuate from year to year resulting in slight changes to the overall burden.
- During the last report it was estimated that this number was 8,963. When the last set of numbers was calculated, FDA was still using a paper based system to register and list firms. On October 1, 2007, FDA switched to an electronic system for registration and listing. Also at that time the Food and Drug Administration Amendments Act of 2007 instituted an establishment registration fee for some types of facilities. FDA believes that during the FY 2008 annual registration cycle, establishments that had previously registered but were not required to do so, removed themselves from inventory of active establishments. FDA believes that the current figures reported by the electronic system more accurately reflect the inventory of registered establishments.
- Potentially affected establishments: Except for manufacturers, not every type of firm is subject to every CGMP/QS requirement. For example, all are subject to Quality Policy (§ 820.20(a)), Document Control (§ 820.40), and other requirements, whereas only manufacturers and specification developers are subject to Subpart C, Design Controls. The type of firm subject to each requirement was identified by the ERG.
- FDA estimated the burden hours (and costs) for the previous CGMP regulation in 1992. That estimate was submitted to OMB on May 4, 1992, under OMB Paperwork Reduction Act Control Number 0910–0073. It was approved by OMB on July 16, 1992, and expired on June 30, 1995. The methodology used is different than that used by ERG in estimating incremental tasks when the new CGMP/QS became final rule. Nevertheless, the agency believes its 1992 estimate adequately represents labor hours (and costs) needed to comply with previous CGMP requirements carried over into the new CGMP/QS regulation. The 1992 estimate used 9,289 respondents (rather than 8,924 respondents), which compensates for differences in methodology.

Dated: June 18, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–15338 Filed 6–23–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0180]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adoption of the Food and Drug Administration Food Code by Local, State, and Tribal Governments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 26, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0448. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed

collection of information to OMB for review and clearance.

Adoption of the FDA Food Code by Local, State, and Tribal Governments—42 U.S.C. 243(a) (OMB Control Number 0910–0448)—Extension

FDA has developed its model Food Code to assist and promote consistent implementation of national food safety regulatory policy among the local, State, and tribal governmental agencies that have primary responsibility for the regulation or oversight of retail level food operations. The FDA Food Code provides a scientifically sound technical and legal basis for regulating the retail segment of the food industry. Authority for providing such assistance is derived from section 311(a) of the Public Health Service Act (42 U.S.C. 243(a)). Under 31 U.S.C. 1535, FDA provides assistance to other Federal agencies such as the Indian Health Service (IHS).

Nationwide adoption of the model FDA Food Code is an important step toward the agency's goal for consistent, scientifically sound, and risk-based food safety standards and practices. A current, comprehensive, and accurate inventory of food code adoptions by States and U.S. territories, local, and tribal governments is necessary to determine the status of up-to-date protection of the U.S. population and to identify areas where assistance to these governments may promote the adoption of regulations based on the FDA Food Code.

This collection effort, which began in 2001, has had remarkable success with 97 percent participation from State and territorial governmental agencies. FDA contracted with the Association of Food and Drug Officials (AFDO) to conduct the initial survey using the OMB approved survey form. The rulemaking process that local, State, territorial, and tribal governmental agencies must follow to adopt the model FDA Food Code is often a long and complicated process that can extend for several years. For this reason, many agencies have reported that they are still in the rulemaking process to adopt or update their food codes. Thus, FDA believes that extension of OMB approval of the survey is needed in order to keep the current database accurate and up-to-date. The contractor will collect the information electronically and/or telephonically and will be able to provide respondents with previous survey responses already in the database. Respondents to this information collection are States and U.S. territories, local, and tribal governmental agencies.

In the **Federal Register** of April 14, 2010 (71 FR 19405), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Food Code Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Respondents	75	4	300	1	300

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on FDA's experience and the number of updates received in the past 3 years. FDA estimates that 75 respondents will provide four quarterly updates each, resulting in an estimated 300 total annual responses. The agency estimates that each quarterly update will take about 1 hour. Of the 75 respondents, those who amend their regulations with changes unrelated to the risk factors and interventions, and those who are not adopting model FDA Food Code provisions, but are incorporating certain Conference for Food Protection recommendations only, will likely need only annual contact.

Dated: June 18, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–15337 Filed 6–23–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Establishment

Pursuant to Section 10413, Part V of the Patient Protection and Affordable Care Act (which established Section 399NN of the Public Health Service Act, as amended); Public Law 111–48, the Director, Centers for Disease Control and Prevention (CDC), announces the establishment of the Advisory Committee on Breast Cancer in Young Women.

This committee is established to assist in creating a national evidence-based public education and media campaign to provide age-appropriate messages and materials to: (1) Increase awareness of good breast health habits; (2) identify risk factors based on familial, racial ethnic and cultural backgrounds; (3) encourage young women and healthcare professionals to increase early detection of breast cancers; and (4) increase the availability of health information and other resources for young women diagnosed with breast cancer.

The Advisory Committee on Breast Cancer in Young Women will advise the Secretary, HHS, the Assistant Secretary for Health, and the Director, CDC regarding the formative research, development, implementation and evaluation of evidence-based activities designed to prevent breast cancer (particularly among those at heightened risk) and promote the early detection and support of young women who develop the disease. The advice provided by the Committee will assist in ensuring scientific quality, timeliness, utility, and dissemination of credible appropriate messages and resource materials.

For more information, contact Ena Wanliss, M.S., Lead Public Health Advisor, CDC, National Center for Chronic Disease Prevention and Health Promotion, Division of Cancer Prevention and Control, 4770 Buford Highway, Mailstop K–57, Chamblee, Georgia 30316, Telephone: 770–488–4225.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 18, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010–15293 Filed 6–23–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Legislative Changes to Primary Care Loan Program Authorized Under Title VII of the Public Health Service Act

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: On March 23, 2010, President Obama signed into law the Affordable Care Act (ACA), Public Law 111–148. Section 5201 of the ACA changes the Primary Care Loan (PCL) program by: (1) Reducing the number of years for the primary health care service requirement; (2) lowering the interest rate for service default; and (3) eliminating the HHS requirement that parental financial information be submitted for independent students.

SUPPLEMENTARY INFORMATION: The PCL program was created through the Health Professions Education Extension Amendments of 1992 (Pub. L. 102–408), which established a new requirement for the use of the Health Professions Student Loan funds for allopathic and osteopathic schools. The PCL program strives to increase the number of primary care physicians by providing long-term, low interest rate loans to full-time students with financial need pursuing a degree in allopathic or osteopathic medicine. Below are details on how the ACA changes Section 723 of the Public Health Service Act (PHSA) regarding administration of the PCL program.

Primary Health Care Service Requirement

Under the PCL program, students were required to enter and complete a residency training program in primary health care and practice in primary health care until the PCL borrower's loan was repaid in full. The ACA change requires that for any new PCLs made on or after March 23, 2010, the PCL borrowers are to enter and complete residency training in primary health care and practice in primary health care for either 10 years (including the years spent in residency training) or through the date on which the loan is repaid in full, whichever occurs first. (Section 5201(a)(1)(B) of the ACA).

Service Default Interest Rate

In the past, PCL borrowers who did not fulfill the service requirements and began practicing in a discipline or specialty other than primary health care were penalized by having their interest rate on the PCL recalculated at 18 percent. The ACA change requires that borrowers who receive a PCL on or after March 23, 2010, and fail to comply with the service requirements of the program will have their loans begin to accrue interest at an annual rate of 2 percent greater than the rate the student would pay if compliant. (Section 5201(a)(3) of the ACA.)

Parental Financial Information Requirement for Independent Students

Prior to enactment of the new law, independent students were required to provide parental financial information to the school's financial aid office so that the school could consider all financial resources available to the independent student for a PCL. The ACA change eliminates the HHS requirement for independent students to provide parental financial information to determine financial need. At its discretion, a school may still require parental financial information for independent students seeking a PCL. (Section 5201(b) of the ACA.) For this program, an independent student is a student who is at least 24 years of age and has been independent for a minimum of 3 years. Dependent students are still required to submit parental financial information.

The ACA changes to the PCL program will require a participating school to revise its PCL master promissory note for new loans made on or after March 23, 2010, to be consistent with the ACA.

Dated: June 21, 2010.

Mary K. Wakefield,

Administrator.

[FR Doc. 2010–15354 Filed 6–23–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2009–M–0317, FDA–2009–M–0369, FDA–2009–M–0370, FDA–2009–M–0485, FDA–2009–M–0536, FDA–2009–M–0540]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993, 301–796–6570.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and

Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from July 1, 2009, through September 30, 2009, and from October 1, 2009, through December 31, 2009. There were no denial actions during either period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JULY 1, 2009, THROUGH DECEMBER 31, 2009.

PMA No. Docket No.	Applicant	Trade Name	Approval Date
P070022 FDA–2009–M–0317	Hologic, Inc.	ADIANA PERMANENT CONTRACEPTION SYSTEM	July 6, 2009
P060008/S11 FDA–2009–M–0369	Boston Scientific Corp.	TAXUS LIBERTE LONG PACLITAXEL ELUING STENT SYSTEM	July 13, 2009
P030050/S2 FDA–2009–M–0370	Sanofi Aventis, LLC	SCULPTRA AESTHETIC	July 28, 2009
P080013 FDA–2009–M–0485	Confluent Surgical, Inc.	DURASEAL XACT SEALANT SYSTEM	September 4, 2009
P080008 FDA–2009–M–0536	bioMerieux, Inc.	VIDAS FREE PSA RT (fPSA) ASSAY	October 8, 2009
P030042 FDA–2009–M–0540	Wright Medical Technology, Inc.	CONSERVE PLUS TOTAL RESURFACING HIP SYSTEM	November 3, 2009

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html*.

Dated: June 17, 2010.

Nancy Stade,

Acting Associate Director for Regulations and Policy, Center for Devices and Radiological Health.

[FR Doc. 2010–15259 Filed 6–23–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel National Childrens Study.

Date: July 12, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Sathasiva B. Kandasamy, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–9304, (301) 435–6680, *skandasa@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: June 18, 2010.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–15311 Filed 6–23–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant

applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Geisha.
Date: July 13, 2010.
Time: 2 p.m. to 4 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).
Contact Person: Norman Chang, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, (301) 496–1485, *changn@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS).

Dated: June 18, 2010.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–15309 Filed 6–23–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel Slack and Slick Channels.
Date: July 12, 2010.
Time: 12:30 p.m. to 3:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852.
Contact Person: Norman Chang, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, (301) 496–1485, *changn@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: June 18, 2010.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–15312 Filed 6–23–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: AIDS and Related Research Integrated Review Group; AIDS Immunology and Pathogenesis Study Section.
Date: July 16, 2010.
Time: 8 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: The Westin Seattle, 1900 5th Avenue, Seattle, WA 98101.
Contact Person: Mary Clare Walker, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435–1165, *walkermc@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–08–160: Metabolic Effects of Psychotropic Medications.
Date: July 20, 2010.
Time: 1 p.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Robert Garofalo, PhD, Scientific Review Officer, Center for Scientifice Review, National Institute of Health, 6701 Rockledge Drive, Room 6156, MSC 7892, Bethesda, MD 20892, 301–435–1043, *garofalors@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 18, 2010.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–15314 Filed 6–23–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Dermatologic and Ophthalmic Drugs Advisory Committee; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee scheduled for June 28, 2010, is cancelled. This meeting was announced in the **Federal Register** of May 11, 2010 (75 FR 26264). The meeting was to discuss new drug application (NDA) 22–340, voclosporin 10-milligram capsules, by Lux Biosciences Inc. This meeting has been cancelled to allow time for the resolution of several outstanding issues. The agency intends to continue evaluating NDA 22–340 and, as needed, may schedule an advisory committee meeting in the future.

FOR FURTHER INFORMATION CONTACT: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, e-mail: *Yvette.Waples@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512534. Please call the Information Line for up-to-date information on this meeting.

Dated: June 18, 2010.

Thinh Nguyen,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–15352 Filed 6–23–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on August 26, 2010, from 8 a.m. to 6 p.m.

Location: Holiday Inn College Park, Grand Ballroom, 1000 Baltimore Ave., College Park, MD.

Contact Person: Margaret McCabe-Janicki, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring, MD 20993–0002, 301–796–7029, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512519. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On August 26, 2010, the committee will discuss, make recommendations, and vote on premarket approval application for MelaFind, sponsored by MELA Sciences, Inc. MelaFind is a non-invasive computer vision system intended to assist in the evaluation of pigmented skin lesions, including atypical moles, which have one or more clinical or historical characteristics of melanoma, before a final decision to biopsy has been rendered. MelaFind acquires and displays multi-spectral (from blue to near infrared) digital images of pigmented skin lesions and uses automatic image analysis and statistical pattern recognition to help identify lesions to be considered for biopsy to rule out melanoma.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 17, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 5, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 10, 2010.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 301–796–5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 18, 2010.

Thinh Nguyen,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–15351 Filed 6–23–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, July 14, 2010, 8:30 a.m. to July 15, 2010, 5 p.m., State Plaza Hotel, 2117 E Street, NW., Washington, DC 20037 which was published in the **Federal Register** on June 14, 2010, 75 FR 33626–33627.

The meeting will be held July 13, 2010 to July 14, 2010. The meeting time and location remain the same. The meeting is closed to the public.

Dated: June 18, 2010.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–15313 Filed 6–23–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Recruitment of Sites for Assignment of National Health Service Corps (NHSC) Personnel Obligated Under the NHSC Scholarship Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: General notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that the listing of entities, and their Health Professional Shortage Area (HPSA) scores, that will receive priority for the assignment of National

Health Service Corps (NHSC) scholarship recipients (NHSC Personnel, NHSC members) during the period July 1, 2010, through June 30, 2011, is posted on the NHSC Web site at *http://nhscjobs.hrsa.gov/*. This list specifies which entities are eligible to receive assignment of NHSC members who are participating in the NHSC Scholarship Program. Please note that not all vacancies associated with sites on the list described below will be for NHSC members, but could be for NHSC Scholarship Program participants serving their obligation through the Private Practice Option.

Eligible HPSAs and Entities

To be eligible to receive assignment of NHSC personnel, entities must: (1) Have a current HPSA designation by the Office of Shortage Designation, Bureau of Health Professions, HRSA; (2) not deny requested health care services, or discriminate in the provision of services to an individual because the individual is unable to pay for the services or because payment for the services would be made under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP); (3) enter into an agreement with the State agency that administers Medicaid and CHIP, accept assignment under Medicare, see all patients regardless of their ability to pay, and use and post a discounted fee plan; and (4) be determined by the Secretary to have: (a) a need and demand for health manpower in the area; (b) appropriately and efficiently used NHSC members assigned to the entity in the past; (c) general community support for the assignment of NHSC members; (d) made unsuccessful efforts to recruit; (e) a reasonable prospect for sound fiscal management by the entity with respect to NHSC members assigned there; and (f) demonstrated a willingness to support and facilitate mentorship, professional development, and training opportunities for NHSC members. Priority in approving applications for assignment of NHSC members goes to sites that: (1) Provide primary medical care, mental health, and/or oral health services to a primary medical care, mental health, or dental HPSA of greatest shortage, respectively; (2) are part of a system of care that provides a continuum of services, including comprehensive primary health care and appropriate referrals or arrangements for secondary and tertiary care; (3) have a documented record of sound fiscal management; and (4) will experience a negative impact on its capacity to provide primary health services if a NHSC member is not assigned to the entity.

Entities that receive assignment of NHSC personnel must assure that: (1) the position will permit the full scope of practice and that the clinician meets the credentialing requirements of the State and site; and (2) the NHSC member assigned to the entity is engaged in full-time clinical practice at the approved service location. For all health professionals except those noted below, "full-time clinical practice" means a minimum of 40 hours per week with at least 32 hours per week spent providing direct patient care in outpatient ambulatory care setting(s) at the approved practice site(s), during normally scheduled office hours. The remaining 8 hours of the minimum 40 hours per week must be spent providing clinical services for patients in the approved practice site(s), or providing clinical services in alternative settings (e.g., hospitals, nursing homes, shelters) as directed by the approved practice site(s), or performing practice-related administrative duties not to exceed 8 hours per week. For obstetricians/gynecologists, certified nurse midwives (CNMs), family practitioners who practice obstetrics on a regular basis, psychiatrists, pediatric dentists, and providers of geriatric services, at least 21 of the minimum 40 hours per week must be spent providing direct patient care (direct patient counseling for psychiatrists) in the outpatient ambulatory care setting(s) at the approved practice site(s), during normally scheduled office hours. The remaining 19 hours of the minimum 40 hours per week must be spent providing clinical services for patients in the approved practice site(s), or providing clinical services in alternative settings (e.g., hospitals, nursing homes, shelters) as directed by the approved practice site(s), or performing practice-related administrative activities (not to exceed 8 hours per week). For all NHSC Scholars, time spent on-call does not count toward the 40 hours per week. In addition, sites receiving assignment of NHSC personnel are expected to: (1) Report to the NHSC all absences, including those in excess of the authorized number of days (up to 35 work days or 280 hours per service year); (2) report to the NHSC any change in the status of an NHSC clinician at the site; (3) provide the time and leave records, schedules, and any related personnel documents for NHSC assignees (including documentation, if applicable, of the reason(s) for the termination of an NHSC clinician's employment at the site prior to his or her obligated service end date); and (4) submit a Uniform Data System (UDS) report. The UDS system allows the site to assess the age, sex, race/ethnicity of, and provider encounter records for, its user population. The UDS reports are site specific. Providers fulfilling NHSC commitments are assigned to a specific site or, in some cases, more than one site. The scope of activity to be reported in UDS includes all activity at the site(s) to which the NHSC member is assigned.

Evaluation and Selection Process

In order for a site to be eligible for placement of NHSC personnel, it must be approved by the NHSC following the site's submission of a Multi-Year Recruitment and Retention (R&R) Assistance Application. The R&R Application approval is good for a period of 3 years from the date of approval.

In approving applications for the assignment of NHSC members, the Secretary shall give priority to any such application that is made regarding the provision of primary health services to a HPSA with the greatest shortage. For the program year July 1, 2010, through June 30, 2011, HPSAs of greatest shortage for determination of priority for assignment of NHSC scholarship-obligated NHSC personnel will be defined as follows: (1) Primary medical care HPSAs with scores of 17 and above are authorized for the assignment of NHSC scholarship recipients who are primary care physicians, family nurse practitioners (NPs), or CNMs; (2) mental health HPSAs with scores of 17 and above are authorized for the assignment of NHSC scholarship recipients who are psychiatrists; (3) primary medical care HPSAs with scores of 15 and above are authorized for the assignment of NHSC scholarship recipients who are physician assistants (PAs); (4) dental HPSAs with scores of 17 and above are authorized for the assignment of NHSC scholarship recipients who are dentists. The NHSC has determined that a minimum HPSA score of 15 for Physician Assistants, and 17 for all other eligible clinicians will enable it to meet its statutory obligation to identify a number of approved service sites at least equal to, but not greater than, twice the number of NHSC scholars available to serve in the 2010–2011 placement cycle.

The number of new NHSC placements through the Scholarship Program allowed at any one site is limited to the following:

(1) Primary Medical Care

No more than 1 physician (MD or DO); and no more than 1 NP, PA, or CNM.

(2) Dental

No more than 1 dentist.

(3) Mental Health

No more than 1 psychiatrist.

Application Requests, Dates and Address

The list of HPSAs and entities that are eligible to receive priority for the placement of NHSC personnel may be updated periodically. Entities that no longer meet eligibility criteria, including those sites whose NHSC 3-year approval has lapsed or whose HPSA designation has been proposed for withdrawal will be removed from the priority listing. New entities interested in being added to the high priority list must submit a Multi-Year NHSC R&R Assistance Application to: National Health Service Corps, 5600 Fishers Lane, Room 8A–30, Rockville, MD 20857, fax 301–594–9009.

Entities interested in receiving application materials may do so by calling the HRSA call center at 1–800–221–9393. They may also get information and download application materials at: *http://nhsc.hrsa.gov/communities/apply.htm.*

A listing of HPSAs and their scores is posted at *http://hpsafind.hrsa.gov/.*

Additional Information

Entities wishing to provide additional data and information in support of their inclusion on the proposed list of HPSAs and entities that would receive priority in assignment of scholarship-obligated NHSC members must do so in writing no later than July 26, 2010. This information should be submitted to: Lori Roche, Acting Director, Division of Site and Clinician Recruitment, Bureau of Clinician Recruitment and Service, 5600 Fishers Lane, Room 8A–55, Rockville, MD 20857 or faxed to: 301–480–4577, attention: Lori Roche. This information will be considered in preparing the final list of HPSAs and entities that are receiving priority for the assignment of scholarship-obligated NHSC personnel.

Paperwork Reduction Act: The R&R Assistance Application has been approved by the Office of Management and Budget under the Paperwork Reduction Act. The OMB clearance number is 0915–0230 and expires September 30, 2011.

The program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100).

Dated: June 21, 2010.

Mary K. Wakefield,

Administrator.

[FR Doc. 2010–15356 Filed 6–23–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 75 FR 12559 dated March 16, 2010).

This notice reflects organizational changes in the Health Resources and Services Administration. Specifically, this notice updates the functional statement for the Office of Acquisitions Management and Policy (RB3) within the Office of Operations (RB).

Chapter RB3, Office of Acquisitions Management and Policy

Section RB3–10, Organization

Delete in its entirety and replace with the following:

The Office of Acquisitions Management and Policy (RB3) is headed by the Director who reports directly to the Chief Operating Officer, Health Resources and Services Administration. The Office of Acquisitions Management and Policy (RB3) includes the following components:

(1) Immediate Office of the Director (RB3);

(2) Division of Contract Services for Primary Care, Health Systems and Clinician Recruitment and Retention (RB35);

(3) Division of Contract Services for Maternal and Child Health and Administrative Support Offices (RB36);

(4) Division of Contact Services for HIV/AIDS, Health Professions, Rural Health and Grants Management (RB37); and

(5) Division of Contracts Administration (RB38).

Section RB3–20, Functions

(1) Delete the functions for the Office of Acquisitions Management and Policy (RB3) in its entirety and replace with the following:

Office of Acquisitions Management and Policy (RB3)

(1) Provides leadership in the planning, development, and implementation of policies and procedures for contracts; (2) exercises the sole responsibility within HRSA for the award and management of contracts; (3) provides advice and consultation of interpretation and application of the Department of Health and Human Services' policies and procedures governing contracts management and inter/intra agency agreements; (4) develops operating procedures and policies for the Agency's contracts programs and inter/intra agency agreements; (5) establishes standards, guides and evaluation procedures for contract operations throughout the Agency; (6) coordinates the Agency's positions and actions with respect to the audit of contracts; (7) maintains liaison directly with or through Agency Bureaus or Offices with contractors, other organizations, and various components of the Department; (8) provides leadership, guidance, and advice on the promotion of the activities in HRSA relating to procurement and material management governed by the Small Business Act of 1958, Executive Order 11625, other statutes and national policy directives for augmenting the role of private industry, small and minority businesses as sources of supply to the Government and Government contractors; and (9) plans, directs, and coordinates the Agency's sourcing program.

Division of Contract Services for Primary Care, Health Systems and Clinician Recruitment and Retention (RB35)

(1) Responsible for providing comprehensive acquisition services including planning, soliciting, negotiating, awarding, and administering simplified and negotiated procurement actions tailored to the following functions in HRSA:

a. Funding health centers in communities, providing access to high quality, family oriented, comprehensive primary and preventive health care for people who are low income, uninsured, or living where health care is scarce;

b. Helping underserved communities and facilities experiencing critical shortages of health care providers, recruit and retain clinicians through scholarship and educational loan repayment opportunities in exchange for service; and

c. Protecting the public health and promoting practices that improve

personal health, including organ, bone marrow and cord blood donation.

(2) Ensures compliance with Federal laws and regulations, departmental and Agency guidelines, policies and procedures; (3) utilizes the automated contracts reporting systems including data input, data accuracy assessments, review and correction of data reports; (4) provides professional, in-depth advice and consultation, customized to the Bureaus/Offices named above, regarding the appropriate contract vehicles and the various phases of the acquisition cycle; (5) conducts pre-award reviews of proposed contracts that exceed the requirements called for in the Federal and departmental acquisition regulations in conjunction with the other Contract Services Customer Divisions; (6) plans and coordinates acquisition reviews of contracting activities within HRSA headquarters and the field components; and (7) responds to congressional inquiries and requests for acquisition information from other Federal agencies and non-Federal sources.

Division of Contract Services for Maternal and Child Health and Administrative Support Offices (RB36)

(1) Responsible for providing comprehensive acquisition services including planning, soliciting, negotiating, awarding, and administering simplified and negotiated procurement actions tailored to the following functions in HRSA:

a. Improving the health of mothers, children and their families as authorized under Title V of the Social Security Act;

b. Information technology services including translating HRSA business needs into effective technical solutions, using proven methodologies to minimize costs, reduce risks, and shorten application development times;

c. Financial and operational services including budget execution and formulation, procurement, facilities, workforce management, issuance of financial policies, managing HRSA's internal and external communications, coordinating HRSA's actions on legislation, special health affairs, equal opportunity, civil rights and diversity management, planning analysis and evaluation; and

d. Partnering with key stakeholders in regions around the Nation to increase access to quality health care, reduce disparities and improve various dimensions of public health.

(2) Ensure compliance with Federal laws and regulations, departmental and Agency guidelines, policies and procedures; (3) utilizes the automated contracts reporting systems including data input, data accuracy assessments, review and correction of data reports; (4) provides professional, in-depth advice and consultation, customized to the Bureaus/Offices named above, regarding the appropriate contract vehicles and the various phases of the acquisition cycle; (5) conducts pre-award reviews of proposed contracts that exceed the requirements called for in the Federal and departmental acquisition regulations in conjunction with the other Contract Services Customer Divisions; (6) plans and coordinates acquisition reviews of contracting activities within HRSA headquarters and the field components; and (7) responds to congressional inquiries and requests for acquisition information from other Federal agencies and non-Federal sources.

Division of Contract Services for HIV/AIDS, Health Professions, Rural Health and Grants Managements (RB37)

(1) Responsible for providing comprehensive acquisition services including planning, soliciting, negotiating, awarding, and administering simplified and negotiated procurement actions tailored to the following functions in HRSA:

a. Increasing the access to health care by developing, distributing and retaining a diverse, culturally competent health workforce;

b. Administering the Ryan White HIV/AIDS Program, the largest Federal program focused exclusively on HIV/AIDS care;

c. Providing grant funding information and services; and

d. Promoting better health care service and seeking solutions to health care problems in rural America.

(2) Ensure compliance with Federal laws and regulations, departmental and Agency guidelines, policies and procedures; (3) utilizes the automated contracts reporting systems including data input, data accuracy assessments, review and correction of data reports; (4) provides professional, in-depth advice and consultation, customized to the Bureaus/Offices named above, regarding the appropriate contract vehicles and the various phases of the acquisition cycle; (5) conducts pre-award reviews of proposed contracts that exceed the requirements called for in the Federal and departmental acquisition regulations in conjunction with the other Contract Services Customer Divisions; (6) plans and coordinates acquisition reviews of contracting activities within HRSA headquarters and the field components; and (7) responds to congressional inquiries and requests for acquisition information from other Federal agencies and non-Federal sources.

Division of Contracts Administration (RB38)

(1) Administers the training and certification programs in collaboration with HRSA's programs and offices for HRSA's Contracting Officers' Technical Representatives (COTRS), FAC–C acquisition professionals, and P/PM Program Managers; (2) administers and oversees HRSA's automated contracts reporting systems; (3) manages the inter/intra agency agreement process; (4) manages the close out process of negotiated and simplified acquisition actions and other related actions; (5) conducts and monitors the performance of the HRSA purchase card program for headquarters, satellite contracts office, and regional field offices; (6) develops and implements policies, procedures, and other internal controls in compliance with Federal, departmental, and Agency acquisition laws, regulations, policies and procedures; (7) coordinates and responds to acquisition-related information requests including congressional inquiries and requests for information from other departments and non-Federal sources; (8) conducts cost analysis for HRSA's acquisition actions in coordination with the Contract Services Divisions of OAMP; and (9) conducts independent reviews and analysis requested by external and internal customers.

Section RB3–30, Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon signature.

Dated: June 17, 2010.

Mary K. Wakefield,

Administrator.

[FR Doc. 2010–15253 Filed 6–23–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Distribution of Continued Dumping and Subsidy Offset to Affected Domestic Producers (CDSOA)

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security

ACTION: 30-Day notice and request for comments; Revision of an existing information collection: 1651–0086.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Distribution of Continued Dumping and Subsidy Offset to Affected Domestic Procedures. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with a change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (75 FR 16493) on April 1, 2010, allowing for a 60-day comment period. One comment was received. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before July 26, 2010.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

SUPPLEMENTARY INFORMATION:

U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104–13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of The proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological techniques or other forms of information.

Title: Distribution of Continued Dumping and Subsidy Offset to Affected Domestic Producers (CDSOA).

OMB Number: 1651–0086.

Form Number: 7401.

Abstract: This collection of information is required to implement the Continued Dumping and Subsidy Offset Act of 2000 (CDSOA). This Act prescribes the administrative procedures, including the time and manner, under which antidumping and countervailing duties assessed on imported products are distributed to affected domestic producers that petitioned for or supported the issuance of the order under which the duties were assessed. The amount of any distribution afforded to these domestic producers is based upon certain qualifying expenditures that they incur after the issuance of the order or finding. This distribution is known as the continued dumping and subsidy offset. The claims process for the CDSOA program is provided for in 19 CFR 159.61 and 159.63.

CBP Form 7401 captures the information from claimants that CBP needs to determine how the distributions are made. This form is published in the **Federal Register** each year in order to inform claimants that they can make claims under the CDSOA program and also provide them with a copy of the form. The form can also be submitted electronically through *http://www.pay.gov.*

In order to expedite the distribution process, CBP proposes to add two data elements to both the paper form and the electronic form, including: "Start Date of Qualifying Expenditures" and "End Date of Qualifying Expenditures".

Current Actions: This submission is being made to extend the expiration date with a revision to Form 7401 and to the on-line application.

Type of Review: Revision and extension of an existing information collection.

Affected Public: Businesses.

Estimated Number of Respondents: 2,000.

Estimated Time per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 2,000.

If additional information is required contact: Tracey Denning, U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street, NW., 7th floor, Washington, DC 20229–1177, at 202–325–0265.

Dated: June 21, 2010.

Tracey Denning,

Agency Clearance Officer,

U.S. Customs and Border Protection.

[FR Doc. 2010–15303 Filed 6–23–10; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2010–0535]

Certificate of Alternative Compliance for the Offshore Supply Vessel SOUTHERN CROSS

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard announces that a Certificate of Alternative Compliance was issued for the offshore supply vessel SOUTHERN CROSS as required by 33 U.S.C. 1605(c) and 33 CFR 81.18.

DATES: The Certificate of Alternate Compliance was issued on June 7, 2010.

ADDRESSES: The docket for this notice is available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to *http://www.regulations.gov,* inserting USCG–2010–0535 in the "Keyword" box, pressing Enter, and then clicking "Search."

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call LTJG Christine Dimitroff, District Eight, Prevention Branch, U.S. Coast Guard, telephone 504–671–2176. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

A Certificate of Alternative Compliance, as allowed for under Title 33, Code of Federal Regulation, Parts 81 and 89, has been issued for the offshore supply vessel SOUTHERN CROSS, O.N. 1223869. Full compliance with 72 COLREGS and the Inland Rules Act would hinder the vessel's ability to conduct loading and unloading operations, and would hinder the vessel's ability to maneuver within close proximity to offshore platforms. Placing the aft masthead light at the horizontal distance from the forward masthead light as required by Annex I, paragraph 3(a) of the 72 COLREGS, and Annex I, Section 84.05(a) of the Inland Rules Act, would result in an aft masthead light location directly over the aft cargo deck where it would interfere with loading and unloading operations and would make the mast highly susceptible to damage during such operations. Therefore, the horizontal distance between the forward and aft masthead lights may be 23'''–1⅛'', placing the aft masthead light over the pilot house.

In addition, due to the design of the vessel it would be difficult and impractical to build a supporting structure that would put the side lights within 10% inboard from the greatest breadth of the vessel, as required by Annex I, paragraph 3(b) of the 72 COLREGS and Annex I, Section 84.05(b), of the Inland Rules Act. Compliance with the rule would cause the side lights to be in a location which would be highly susceptible to damage from offshore platforms.

Locating the side lights 7'''– 9⅝'' inboard from the greatest breadth of the vessel on the pilot house will provide a sheltered location for the lights and allow maneuvering within close proximity to offshore platforms.

The Certificate of Alternative Compliance allows for the placement of the side lights to deviate from requirements set forth in Annex I, paragraph 3(b) of 72 COLREGS, and Annex I, paragraph 84.05(b) of the Inland Rules Act. In addition, the Certificate of Alternative Compliance allows for the horizontal separation of the forward and aft masthead lights to deviate from the requirements of Annex I, paragraph 3(a) of 72 COLREGS, and Annex I, Section 84.05(a) of the Inland Rules Act.

This notice is issued under authority of 33 U.S.C. 1605(c), and 33 CFR 81.18.

Dated: June 8, 2010.

RS Keister,

Commander, U.S. Coast Guard, Chief, Inspections Section, By Direction of the Commander, Eighth Coast Guard District.

[FR Doc. 2010–15275 Filed 6–23–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent to Repatriate Cultural Items: U.S. Department of Defense, Army Corps of Engineers, Walla Walla District, Walla Walla, WA and Museum of Anthropology, Washington State University, Pullman, WA

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items in the control of the U.S. Department of Defense, Army Corps of Engineers, Walla Walla District, Walla Walla, WA, and in the possession of the Museum of Anthropology, Washington State University, Pullman, WA, that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the cultural items. The National Park Service is not responsible for the determinations in this notice.

In 1972, cultural items were removed from burials at 45AS2, Asotin County, WA. The cultural items and burials were removed during the Nez Perce Grave Removal Project by the University of Idaho under contract with the Army Corps of Engineers. Following removal, the burials were delivered to the University of Idaho. The human remains were returned to the Nez Perce Tribe and reburied in Spalding, ID, in 1973. Between 1996 and 2000, the cultural items were transferred from the University of Idaho to Washington State University, and are now unassociated funerary objects. The 66 unassociated funerary objects are 34 counted objects and 32 lots of objects. The 34 counted objects are 1 abrader, 1 adze, 1 awl, 3 bifaces, 6 cobble spalls, 5 cores, 2 digging stick handles, 2 flake perforators, 2 hafted drills, 1 piece of incised bone, 7 pestles, 2 projectile points, and 1 fragment of worked bone. The 32 lots of objects are 4 lots of animal remains, 5 lots of antler fragments, 2 lots of antler wedge fragments, 2 lots of antler wedges, 9 lots of flakes, 2 lots of modified flakes, 1 lot of shell beads, 5 lots of shell remains, 1 lot of straight pins, and 1 lot of wood fragments.

In 1975, cultural items were removed from burials at 45CO1, Columbia County, WA. The burials were removed during the Tucannon Burial Relocation Project conducted by the University of Idaho under contract with the Army Corps of Engineers. Following removal, the cultural items and burials were delivered to the University of Idaho. The human remains were reburied in Idaho in 1977. In 2000, the remaining cultural items were transferred from the University of Idaho to Washington State University, and are now unassociated funerary objects. The 653 unassociated funerary objects are 95 counted items and 558 lots of objects. The 95 counted objects are 2 beaver incisors, 4 bifaces, 1 worked bone fragment, 1 bottle fragment, 13 bullet cartridges, 3 copper pendants, 6 cores, 1 digging stick fragment, 8 elk tooth beads, 1 hafted drill, 2 incised bone fragments, 2 incised digging stick fragments, 1 marble, 1 net sinker, 8 stone pestles, 3 pipes, 1 piece of polished stone, 15 projectile points, 3 railroad spikes, 6 scrapers, 4 shell pendants, 2 stone shaft abraders, and 7 pieces of worked bone. The 558 lots of objects are 4 lots of buttons or grommets, 1 lot of ceramic fragments, 3 lots of cigar box fragments, 4 lots of clothing and shoes, 3 lots of cordage fragments, 39 lots of flakes, 47 lots of glass and metal beads, 19 lots of glass fragments, 1 lot of matting fragments, 8 lots of metal can fragments, 30 lots of metal fragments, 1 lot of mussel fragments, 5 lots of nails, 3 lots of paper fragments, 327 lots of shell beads, 12 lots of shell fragments, 29 lots of shell remains, 15 lots of rolled metal tinklers, 3 lots of utilized flakes, and 4 lots of worked bone.

In 1958 and 1959, cultural items were removed from burials at Fishhook Island, 45FR42, Franklin County, WA. In 1958, the Columbia Archaeological Society excavated at Fishhook Island. In 1959, the Washington State University excavated at Fishhook Island while under contract with the National Park Service. The 1958 and 1959 excavations took place before the land was acquired by the Army Corps of Engineers. At an unknown date, the human remains excavated were delivered to the Washington State University and University of Idaho. In 2000, the University of Idaho transferred the

45FR42 materials to Washington State University. In 2006, the Army Corps of Engineers physical anthropologists inventoried the human remains. Some of the human remains collected are not currently in the museum collection, and are believed to have been reburied in 1991. Burials numbers 1 through 21 were consecutively assigned by the Columbia Archaeological Society to their excavations. Washington State University assigned burial numbers 1 through 24 to their excavations. The duplicate burial numbers and scant records do not, in many instances, permit clear association of funerary objects with the burials removed. The 45FR42 burials are estimated to range from the proto-historic/historic time periods to the early 1920s. Native American objects found with the burials include olivella and dentalia shell beads and glass beads. In the early 1900s, local residents witnessed Native American burial ceremonies held on Fishhook Island, and remember Cayuse, Walla Walla, Wallula, and Palus people in the general area during the late 1880s and early 1900s. Fishhook Island is located within the overlapping 19th century territories of the Palus and the Walla Walla people. The 171 unassociated funerary objects are 80 counted objects and 91 lots of objects. The 80 counted objects are 27 cobble spalls, 1 core, 23 elk tooth beads, 2 beaver incisors, 6 bone awls, 1 digging stick fragment, 1 digging stick handle, 2 hafted drills, 1 adze, 10 preforms, 4 projectile points, and 2 scrapers. The 91 lots of objects are 22 lots of flakes, 3 lots of red ochre, 24 lots of shell beads, 5 lots of shell remains, 7 lots of animal remains, 6 lots of bag residue, 1 lot of charcoal, 2 lots of fire-cracked rock, 5 lots of glass and metal beads, 3 lots of juniper seed beads, 4 lots of matting fragments, 1 lot of metal fragments, 3 lots of plant remains, 1 lot of shell pendant fragments, and 4 lots of wood fragments.

In 1960, cultural items were removed from burials at Ford Island, 45FR47, Franklin County, WA. Washington State University excavated at Ford Island under contract with the Army Corps of Engineers. The burials were delivered to the University of Idaho and Washington State University. The human remains are thought to have been reburied before 1985. In 1992, a Washington State University inventory recorded the presence of Burial 6 materials in the collection. Between 1996 and 2000, the University of Idaho transferred materials to Washington State University. In 2003, the transferred materials were inventoried, and the presence of Burial 9 materials was recorded along with funerary objects from other 45FR47 burials. The burials associated with the 45FR47 collection are Native American as demonstrated by the presence of Native American Plateau objects, Plateau burial patterns, and eyewitness accounts of Indian people living on Ford Island in the 1900s. Dentalia shell beads start to be common in the Plateau archeological record about 3,000 years ago. Glass beads became available to Indian groups from the 1780s through the 1810s. Early and late ethnographic documentation indicates the island is located within the overlapping 19th century territories of the Palus and Walla Walla people. The 165 unassociated funerary objects are 17 counted objects and 148 lots of objects. The 17 counted objects are 2 bells, 1 copper ring, 1 copper screw, 1 hammerstone, 1 metal ring, 2 net sinkers, 1 ochre stained ground stone, 3 shell ornaments, 1 spoon, 1 spoon handle, 1 preform, 1 core, and 1 pipe. The 148 lots of objects are 1 lot of animal remains, 1 lot of bag residue, 3 lots of buttons, 2 lots of charcoal, 21 lots of fabric remains, 5 lots of flakes, 51 lots of glass and metal beads, 2 lots of glass beads, 2 lots of glass fragments, 7 lots of leather fragments, 27 lots of metal fragments, 1 lot of nails, 7 lots of organic remains, l lot of soil, and 17 lots of wood fragments.

In 1963, cultural items were removed from 45WT2, Whitman County, WA. The excavation took place under contract with the National Park Service and before the land was acquired by the Army Corps of Engineers. The cultural items were with Burial 1 when excavated. At an unknown date, the materials associated with this excavation were delivered to Washington State University and the University of Idaho. In 2000, one box of materials was transferred from the University of Idaho to Washington State University. The Burial 1 remains are not labeled and the funerary objects are therefore no longer associated. The three unassociated funerary objects are one counted object and two lots of objects, which are one pestle, one lot of red ochre, and one lot of wood fragments.

In 1977 and 1978, cultural items were removed from burials at 45WT53, Whitman County, WA. In 1977, Burials 1 and 2 were removed by the University of Idaho while under contract with the Army Corps of Engineers. Following removal, the cultural items and burials were delivered to the University of Idaho and Washington State University. In 1978, Burials 3 through 5 were removed by the University of Idaho while under contract to the Army Corps of Engineers as part of the Nez Perce Grave Recovery Project. Following removal, the cultural items and burials were delivered to the University of Idaho and Washington State University. The human remains from both excavations were reburied at Spalding, ID, in 1978. In 2000, the cultural items from both excavations were transferred from the University of Idaho to Washington State University, and are now unassociated funerary objects. The 149 unassociated funerary objects are 17 counted objects and 132 lots of objects. The 17 counted objects are 2 bone pendants, 1 digging stick handle, 2 hammerstones, 1 incised bone fragment, 5 stone beads, 5 stone knives, and 1 tack. The 132 lots of objects are 6 lots of animal remains, 2 lots of bone awl fragments, 23 lots of bone beads, 1 lot of buttons, 4 lots of elk tooth beads, 35 lots of flakes, 44 lots of glass trade beads, 3 lots of leather fragments, 8 lots of shell beads, 2 lots of ochre stained cobbles, 2 lots of red and yellow ochre, and 2 lots of soil.

In 1967, cultural items were removed from burials at the Ferguson Burial Site, 45WT55, Whitman County, WA. The Washington State University field school excavated Burials 1 through 7 prior to land acquisition by the Army Corps of Engineers. The burials were delivered to Washington State University following removal. At an unknown time, the human remains were transferred to the University of Idaho where a pre-NAGPRA program of repatriation was ongoing. In 2000, the University of Idaho transferred the remaining 45WT55 collection back to Washington State University. Site 45WT55 is adjacent to judicially established Nez Perce Indian land and within the overlapping 19th century territories of the Palus and Nez Perce people. The unassociated funerary items are six lots of wood fragments.

In 1971, cultural items were removed from burials at 45WT101, Whitman County, WA. The University of Idaho removed 33 burials while under contract to the Army Corps of Engineers as part of the Nez Perce Grave Removal Project. The 45WT101 burials were reported as reburied at Spalding, ID, in 1978. In 1998 and 2000, the University of Idaho transferred the collection to Washington State University. In 2001, during a collections assessment inventory, the Washington State University encountered cultural items associated with many of the burials. The cultural items are now unassociated funerary objects. The 88 unassociated funerary objects are 24 counted objects and 64 lots of objects. The 24 counted objects are 2 abalone shell pendants, 1 abrading stone, 1 biface, 4 bone gaming

pieces, 1 incised stone, 1 nipple topped maul, 1 modified pebble, 6 preforms, 4 projectile points, 1 scraper, and 2 stone pipes. The 64 lots of objects are 1 lot of abalone shell fragments, 3 lots of antler fragments, 21 lots of flakes, 2 lots of red ochre, 24 lots of shell beads, 2 lots of shell remains, and 11 lots of modified wood fragments.

Six lines of evidence - geographical, archeological, anthropological, linguistic, oral tradition, and historical - support cultural affiliation of the Confederated Tribes of the Colville Reservation, Confederated Tribes of the Umatilla Indian Reservation, Confederated Tribes of the Warm Springs Indian Reservation of Oregon, Confederated Tribes and Bands of the Yakama Nation, and the Nez Perce Tribe with the unassociated funerary objects identified in the above-mentioned sites and collections. Additionally, a cultural relationship is determined to exist between the unassociated funerary objects and the Wanapum Band, a non-federally recognized Indian group. Other relevant information provided by the Indian tribes and the Wanapum Band indicates they are direct descendant communities from the Native people that jointly used this area, are intermarried, have enrolled members with documented connections to ancestors buried along the Snake River, and are all part of the more broadly defined Plateau cultural community.

Officials of the U.S. Department of Defense, Army Corps of Engineers, Walla Walla District, have determined that, pursuant to 25 U.S.C. 3001(3)(B), the 1,301 objects, which are 268 counted objects and 1,033 lots of objects, described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of Native American individuals. Officials of the U.S. Department of Defense, Army Corps of Engineers, Walla Walla District, also have determined that, pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Confederated Tribes of the Colville Reservation, Washington; Confederated Tribes of the Umatilla Indian Reservation, Oregon; Confederated Tribes of the Warm Springs Indian Reservation of Oregon; Confederated Tribes and Bands of the Yakama Nation, Washington; and the Nez Perce Tribe, Idaho. Lastly, officials of the U.S. Department of Defense, Army Corps of Engineers, Walla Walla District, have determined that there is a cultural relationship between the unassociated funerary objects and the Wanapum Band, a non-federally recognized Indian group.

Representatives of any other Indian tribe that believes itself to be culturally affiliated to the unassociated funerary objects should contact LTC Michael Farrell, U.S. Department of Defense, Army Corps of Engineers, Walla Walla District, 201 North Third Avenue, Walla Walla, WA 99362, telephone (509) 527–7700, before July 26, 2010. Repatriation of the unassociated funerary objects to the Confederated Tribes of the Colville Reservation, Washington; Confederated Tribes of the Umatilla Indian Reservation, Oregon; Confederated Tribes of the Warm Springs Indian Reservation of Oregon; Confederated Tribes and Bands of the Yakama Nation, Washington; and Nez Perce Tribe, Idaho, may proceed after that date if no additional claimants come forward. Lastly, the U.S. Department of Defense, Army Corps of Engineers, Walla Walla District, acknowledges the participation of the Wanapum Band, a non-federally recognized Indian group, in the transfer of the unassociated funerary objects to the Indian tribes.

The U.S. Department of Defense, Army Corps of Engineers, Walla Walla District, is responsible for notifying the Confederated Tribes of the Colville Reservation, Washington; Confederated Tribes of the Umatilla Indian Reservation, Oregon; Confederated Tribes of the Warm Springs Indian Reservation of Oregon; Confederated Tribes and Bands of the Yakama Nation, Washington; Nez Perce Tribe, Idaho; and the Wanapum Band, a non-federally recognized Indian group, that this notice has been published.

Dated: June 18, 2010

David Tarler,

Acting Manager, National NAGPRA Program.

[FR Doc. 2010–15379 Filed 6–23–10; 8:45 am]

BILLING CODE 4312–50–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent to Repatriate Cultural Items: California Department of Parks and Recreation, Sacramento, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items in the possession of the California Department of Parks and Recreation, Sacramento, CA, that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

In 1962, the Bowles site, CA–BUT–452, in Butte County, CA, was recorded by Francis A. Riddell, possibly as part of the Oroville reservoir survey. Additional Native American human remains and associated funerary objects from Butte County that are in the possession of the California Department of Parks and Recreation are described in a previously published Notice of Inventory Completion (73 FR 20937–20939, April 17, 2008). In the collection, there are 24 Olivella beads, of which 18 are complete, and all are unifacially drilled. Acquisition documents are missing, although a tag indicates these beads are from burial #2. However, there are no human remains from this site in the institution's collection. Therefore, the institution reasonably believes the 24 beads are unassociated funerary objects.

The age of these funerary objects is unknown. They are consistent with the occupation of the site by the historic Konkow (Northwestern Maidu). Generally, archeologists believe that the Penutian-speaking Maidu are descended from what have been identified as the Windmiller people who occupied the Central Valley of California from 3,000 to 4,000 years ago. Geographic affiliation is consistent with the historically documented Konkow (Northwestern Maidu). Descendants of the Konkow (Northwestern Maidu) are members of the Berry Creek Rancheria of Maidu Indians of California; Enterprise Rancheria of Maidu Indians of California; Mechoopda Indian Tribe of Chico Rancheria, California; Mooretown Rancheria of Maidu Indians of California; and Round Valley Indian Tribes of the Round Valley Reservation, California.

Officials of the California Department of Parks and Recreation have determined that, pursuant to 25 U.S.C. 3001(3)(B), the 24 cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite

or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual. Officials of the California Department of Parks and Recreation also have determined that, pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Berry Creek Rancheria of Maidu Indians of California; Enterprise Rancheria of Maidu Indians of California; Mechoopda Indian Tribe of Chico Rancheria, California; Mooretown Rancheria of Maidu Indians of California; and Round Valley Indian Tribes of the Round Valley Reservation, California.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the unassociated funerary objects should contact Rebecca Carruthers, NAGPRA Coordinator, California Department of Parks and Recreation, 1416 Ninth St., Room 902, Sacramento, CA 95814, telephone (916) 653–8893, before July 26, 2010. Repatriation of the unassociated funerary objects to the Berry Creek Rancheria of Maidu Indians of California; Enterprise Rancheria of Maidu Indians of California; Mechoopda Indian Tribe of Chico Rancheria, California; Mooretown Rancheria of Maidu Indians of California; and Round Valley Indian Tribes of the Round Valley Reservation, California, may proceed after that date if no additional claimants come forward.

The California Department of Parks and Recreation is responsible for notifying the Berry Creek Rancheria of Maidu Indians of California; Enterprise Rancheria of Maidu Indians of California; Mechoopda Indian Tribe of Chico Rancheria, California; Mooretown Rancheria of Maidu Indians of California; and Round Valley Indian Tribes of the Round Valley Reservation, California, that this notice has been published.

Dated: June 18, 2010

David Tarler,

Acting Manager, National NAGPRA Program.

[FR Doc. 2010–15287 Filed 6–23–10; 8:45 am]

BILLING CODE 4312–50–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion: New York University College of Dentistry, New York, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains in the possession and control of the New York University College of Dentistry, New York, NY. The human remains were removed from Broward and Levy Counties, FL, and an unknown mound in East Florida.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

A detailed assessment of the human remains was made by the New York University College of Dentistry professional staff in consultation with representatives of the Alabama-Quassarte Tribal Town, Oklahoma; Choctaw Nation of Oklahoma; Jena Band of Choctaw Indians, Louisiana; Kialegee Tribal Town, Oklahoma; Miccosukee Tribe of Indians of Florida; Mississippi Band of Choctaw Indians, Mississippi; Muscogee (Creek) Nation, Oklahoma; Poarch Band of Creek Indians of Alabama; Seminole Nation of Oklahoma; Seminole Tribe of Florida (Dania, Big Cypress, Brighton, Hollywood & Tampa Reservations); and Thlopthlocco Tribal Town, Oklahoma.

In 1937, human remains representing a minimum of one individual were removed from a mound at Lettuce Lake, (8Bd7), Broward County, FL. The mound was excavated by Geoffrey Olson and William C. Orchard as part of an expedition sponsored by the Museum of the American Indian, Heye Foundation. The remains were accessioned by the Museum of the American Indian in 1937. In 1956, the Museum of the American Indian transferred the remains to Dr. Theodore Kazamiroff, New York University College of Dentistry. No known individual was identified. No associated funerary objects are present.

Artifacts recovered from the mound indicate that it dates to the Glades IIIa Period, A.D. 1200-1400, and is a Glades culture site of the Glades Tradition. The morphology of the remains is consistent with an individual of Native American ancestry. There is evidence for cultural continuity between the Glades IIIa Period and the post-contact people of the Broward County area. In the Historic Period, the area around Broward County is identified as Tequesta territory. In 1513, Tequesta villages were described in the records of the Ponce de Leon expedition. The Tequesta suffered from diseases and other disrupting forces of European contact, and, by 1743, a distinct group that could be identified as Tequesta had disappeared. In 1763, the remnant communities of Native Floridians in south Florida were taken to Cuba when Florida was transferred from Spanish to British control.

At an unknown date, human remains representing a minimum of one individual were removed from a mound at Hog Island, Levy County, FL. It is likely that the remains were collected by William Bryant in 1918. The remains from Hog Island were in the collection of William L. Bryant when it was sold to the Museum of the American Indian, Heye Foundation in 1920. In 1956, the Museum of the American Indian transferred the remains to Dr. Theodore Kazamiroff, New York University College of Dentistry. No known individual was identified. No associated funerary objects are present.

Hog Island is located within the North Peninsular Coast region. Florida state site files identify a Weeden Island Period burial mound, 8Lv2, on Hog Island. Artifacts from the mound indicate that it is associated with the Weeden Island 2 phase of the Weeden Island I Period, circa A.D. 150-450. The morphology of the remains is consistent with an individual of Native American ancestry. During the Weeden Island II Period (circa A.D. 600-1200), the North Peninsular coastal region of Florida remained a distinct region. The cultural sequence after A.D. 1200 is difficult to determine. The Safety Harbor culture to the south, the Northwest Florida cultures to the northwest, and Alachua culture to the east abut the region, but do not extend into the Northwest Peninsular Coast area. The early Spanish explorations of Ponce de Leon, Narvaez, and DeSoto did not enter the coastal Northwest Florida Peninsular areas. The Spanish did not establish any missions in the region after claiming La Florida. As a result, there is no information from early colonial documents regarding any people living in this region. This stands in marked contrast to the records for the area from Tampa Bay to the south and for the northwest coast of Florida. There are also no records to identify people from the region in subsequent French or English documents. It is likely that inhabitants of the Northwest Peninsular Coast quickly felt the effects of European diseases that were introduced by the Spanish in the early 16th century. As in other portions of Florida,

their communities probably shrank in size until only a small portion of the original population was left. These people may have sought refuge elsewhere in Florida, but were never identified.

In 1920, human remains representing a minimum of seven individuals were removed from an unidentified mound in East Florida by Charles Hallock. The remains and objects from the mound were loaned by the Long Island Historical Society (now the Brooklyn Historical Society) to the Museum of the American Indian, Heye Foundation in 1920. According to archival records, the loan was made permanent in 1967. In 1956, the Museum of the American Indian transferred the remains to Dr. Theodore Kazamiroff, New York University College of Dentistry. No known individuals were identified. No associated funerary objects are present.

The specific site and age for the remains is not known, but the morphology of the remains is consistent with individuals of Native American ancestry. In prehistoric cultural sequences, the area of eastern Florida is identified with the St. Johns culture, whose territory lay in the portions of eastern and central Florida where the St. Johns River and its tributaries flow. The St. Johns tradition first appeared around 500 B.C. and continued until European contact. It is divided into several periods, all of which include burial mounds. In 16th century records, the people living in the St. Johns River area are identified as the Timucua. Historic mission records suggest that diseases introduced between 1562 and 1595 had decimated the population in the St. Johns River area. Additional epidemics in the first half of the 17th century resulted in massive population loss and changes to the diet, health, economy, and religion of the Timucua. In 1684, the British began to attack the Spanish missions where the Timucua were living in order to gain control of Florida. At the same time, the missions were also subject to slave raiding by tribes from the north. By 1704, all missions but St. Augustine were destroyed and the remaining Timucua took refuge at it. In 1711, only 942 Timucua and Apalachee were living around St. Augustine. Slave raiding, disease, and English attacks further reduced the population; by 1759, only 59 Timucua and Apalachee remained at St. Augustine. The Spanish withdrew from St. Augustine between 1763-1764, taking the 89 Indians from St. Augustine with them to Cuba.

In all three sites mentioned-above, the population vacuum created by the absence of Florida tribal groups opened the state to migration by the Lower Creek. The first Creek settlements were located in northern Florida. Conflicts with the British, and then the American government, pushed the Creek into the southern half of the state. These Creek communities grew independent of Creek nations to the north and became known as the Seminole and Miccosukee.

Officials of the New York University College of Dentistry have determined that, pursuant to 25 U.S.C. 3001(9), the human remains described above represent the physical remains of nine individuals of Native American ancestry. Officials of the New York University College of Dentistry also have determined that, pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot reasonably be traced between the Native American human remains and any present-day Indian tribe.

The Native American Graves Protection and Repatriation Review Committee (Review Committee) is responsible for recommending specific actions for disposition of culturally unidentifiable human remains. In July 2009, the New York University College of Dentistry requested that the Review Committee recommend disposition of the culturally unidentifiable human remains of nine individuals to the Miccosukee Tribe of Indians of Florida. The Review Committee considered the proposal at its October 30-31, 2009, meeting and recommended disposition of the human remains to the Miccosukee Tribe of Indians of Florida.

A March 4, 2010, letter from the Designated Federal Official, writing on behalf of the Secretary of the Interior, transmitted the authorization for the College to effect disposition of the human remains to the Miccosukee Tribe of Indians of Florida contingent on the publication of a Notice of Inventory Completion in the **Federal Register**. This notice fulfills that requirement.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains should contact Dr. Louis Terracio, New York University College of Dentistry, 345 East 24th St., New York, NY 10010, telephone (212) 998–9917, before July 26, 2010. Disposition of the human remains to the Miccosukee Tribe of Indians of Florida may proceed after that date if no additional claimants come forward.

The New York University College of Dentistry is responsible for notifying the Alabama-Quassarte Tribal Town, Oklahoma; Choctaw Nation of Oklahoma; Jena Band of Choctaw Indians, Louisiana; Kialegee Tribal Town, Oklahoma; Miccosukee Tribe of Indians of Florida; Mississippi Band of Choctaw Indians, Mississippi; Muscogee (Creek) Nation, Oklahoma; Poarch Band of Creek Indians of Alabama; Seminole Nation of Oklahoma; Seminole Tribe of Florida (Dania, Big Cypress, Brighton, Hollywood & Tampa Reservations); and Thlopthlocco Tribal Town, Oklahoma, that this notice has been published.

Dated: June 18, 2010

David Tarler,

Acting Manager, National NAGPRA Program.

[FR Doc. 2010–15286 Filed 6–23–10; 8:45 am]

BILLING CODE 4312–50–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion: Cranbrook Institute of Science, Bloomfield Hills, MI

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects in the possession of the Cranbrook Institute of Science, an institutional member of the Cranbrook Educational Community, Bloomfield Hills, MI. The human remains and associated funerary objects were removed from Macomb, Monroe, Oakland, and Wayne Counties, MI.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

A detailed assessment of the human remains was made by the Cranbrook Institute of Science professional staff in consultation with representatives of the Little Traverse Bay Bands of Odawa Indians, Michigan, on behalf of the Michigan Anishnaabek Cultural Preservation and Repatriation Alliance (MACPRA), a non-federally recognized Indian group.

On an unknown date, human remains representing a minimum of one individual were removed from Birmingham, Oakland County, MI. On April 1937, the City Coroner of Birmingham gave the human remains to the museum (CIS reference #116). No

known individual was identified. No associated funerary objects are present.

Museum records indicate that the individual is a female and probably Native American. There was no stratigraphic report or supplemental information available to help determine further cultural affiliation, and thus, the human remains were classified as culturally unidentifiable.

On an unknown date, human remains representing a minimum of one individual were removed from the Gibraltar Site, Monroe County, MI. On February 18, 1938, Darrel J. Richards gave the human remains to the museum (CIS reference #280). No known individual was identified. No associated funerary objects are present.

Originally museum records indicated that, "With no artifacts or temporal information to work with, no consultation could be conducted." Therefore, the human remains were classified as culturally unidentifiable. The individual described above has the same donor, date of donation, and site name as the human remains and associated funerary objects described in the next paragraph, but were assigned different reference numbers.

On an unknown date, human remains representing a minimum of four individuals were removed from the Gibraltar Site, Monroe County, MI. On February 18, 1938, Darrel J. Richards gave the human remains to the museum (CIS reference #281). No known individuals were identified. The 25 associated funerary objects are 24 pottery fragments and 1 container of unidentified material.

The human remains are possibly Native American. Museum records indicate that with "no additional information to work with, no additional no dialog could be initiated." Therefore, the human remains were classified as culturally unidentifiable.

On an unknown date, human remains representing a minimum of three individuals were removed from the New Baltimore Site, Macomb County, MI. On June 13, 1940, the human remains were donated by Gwynn Cushman to the museum (CIS reference #911). No known individuals were identified. No associated funerary objects are present.

According to museum records, the human remains are the co-mingled remains of at least three individuals that date from either the Prehistoric or early Historic Period. Museum records indicate that "no linear descendants could be substantiated; therefore no consultation could be conducted." Thus, the human remains were classified as culturally unidentifiable.

On an unknown date, human remains representing a minimum one individual were removed from Mill Street, Auburn Heights, Oakland County, MI. On April 29, 1951, the human remains were received from Mr. and Mrs. Chester Wade and given to the museum (CIS reference ι6873). No known individual was identified. The eight associated funerary objects are seven pieces of trade silver, including a brooch and several wrist cuffs/bracelets, and a fragment of cloth (CIS reference #6874).

According to museum records, the human remains are probably a female Native American. The file of record indicates that, "even with the trade silver items", "there was no actual indication of stratigraphic or artifact association on which to begin dialogue." Therefore "no consultation could be conducted." These human remains were thus classified as culturally unidentifiable.

On an unknown date, human remains representing a minimum of two individuals were removed from a location in Oakland County, MI. In May 1951, the human remains were given to the museum by an unidentified source (CIS reference #7520). No known individuals were identified. No associated funerary objects are present.

The human remains are the co-mingled remains of at least two individuals that are probably Native American based on context and bone condition. Museum records indicate, "from context and bone condition – not morphology, these skeletal remains might possibly be American Indian but with such little identification and no other information, no consultation could be conducted." Therefore, the human remains were classified as culturally unidentifiable.

On an unknown date, human remains representing a minimum of four individuals were removed from a location in Oakland County, MI. In May 1951, the human remains were given to the museum by an unidentified source (CIS reference #7522). No known individuals were identified. No associated funerary objects are present.

According to museum records the human remains are possibly Native American based on bone condition. The records also indicate that, "from context and bone condition – not morphology, these skeletal remains might possibly be American Indian but with such little identification and no other information, no consultation could be conducted." Therefore, the human remains were classified as culturally unidentifiable.

On an unknown date, human remains representing a minimum of one individual were removed from a location in Oakland County, MI. In May 1951, the human remains were given to the museum by an unidentified source (CIS reference #7523). No known individual was identified. No associated funerary objects are present.

Museum records indicate that, "from context and bone condition – not morphology, these skeletal remains might possibly be American Indian but with such little identification and no other information, no consultation could be conducted." Therefore, the human remains were classified as culturally unidentifiable.

On an unknown date, human remains representing a minimum of one individual were removed from a location in Oakland County, MI. In May 1951, the human remains were given to the museum by an unidentified source (CIS reference #7524). No known individual was identified. No associated funerary objects are present.

According to museum records, the human remains are probably Native American from the Prehistoric or Early Historic Period. Records also indicate that, "from context and bone condition – not morphology, these skeletal remains might possibly be American Indian but with such little identification and no other information, no consultation could be conducted." Therefore, the human remains were classified as culturally unidentifiable.

On an unknown date, human remains representing a minimum of eight individuals were removed from Kennet Road, Pontiac, Oakland County, MI, by the Pontiac Police Department (case number 194312). On April 15, 1968, the human remains were given to the museum by Warren L. Wittry (CIS reference #9734). No known individuals were identified. No associated funerary objects are present.

Museum records indicate that, "With no additional association to use as a basis, no consultation could be conducted." Therefore, the human remains were classified as culturally unidentifiable.

On an unknown date, human remains representing a minimum of one individual were removed from the homestead of Henry Barnes, 822 Shady Hollow Circle, Bloomfield Hills, Oakland County, MI. In the 1960s, the human remains were given to the museum by Warren L. Wittry (CIS reference #9735). No known individual was identified. No associated funerary objects are present.

According to museum records, the human remains are probably a female Native American. Records also indicate that the "remains are too incomplete" and "no beginning was found for the

initiation of consultations." Therefore, the human remains were classified as culturally unidentifiable.

On an unknown date, human remains representing a minimum of one individual were removed from near Coolidge Road, Troy, Oakland County, MI. On November 9, 1963, the human remains were given to the museum by Detective Mortensen, Troy Police Department (CIS reference #9736). No known individual was identified. No associated funerary objects are present.

According to museum records, the individual is a mature male, and probably Native American. Records indicate that no basis was found for the initiation of consultations. Therefore, the human remains were classified as culturally unidentifiable.

On an unknown date, human remains representing a minimum of one individual were removed from near Plymouth, Wayne County, MI. On an unknown date, the museum received the human remains from an unidentified source (CIS reference #9737). No known individual was identified. No associated funerary objects are present.

According to museum records, the human remains are probably a female Native American. Records also indicate that, "no further information was available, no consultation could be conducted." Therefore, the human remains were classified as culturally unidentifiable.

On an unknown date, human remains representing a minimum of two individuals were removed from a site at Hamlin and Rochester Roads, Rochester, Oakland County, MI. On December 17, 1970, the human remains were given to the museum by Dr. John Burton, Oakland County Medical Examiner (CIS reference #9738 and #9739). No known individuals were identified. No associated funerary objects are present.

According to museum records, the human remains are possibly Native American. One of the individuals exhibits a pattern of wear consistent with that known for aboriginal populations. Records also indicate that, "necessary practical information was not available; therefore no consultation could be conducted." Therefore, the human remains were classified as culturally unidentifiable.

On an unknown date, human remains representing a minimum of one individual were removed from an unknown location, but probably in Michigan. On an unknown date, the human remains were given to the museum by an unidentified source (CIS reference #9816). No known individual was identified. No associated funerary objects are present.

According to museum records, the human remains are probably Native American based on femoral shaft morphology. Records also indicate that geographical and collection data were not available, and therefore, no consultation could be conducted. Thus, the human remains were classified as culturally unidentifiable.

On an unknown date, human remains representing a minimum of one individual were removed from an unknown location, but probably in Michigan. On an unknown date, the human remains were given to the museum by an unidentified source (CIS reference #9817). No known individual was identified. No associated funerary objects are present.

According to museum records, the human remains are probably a female Native American based on femoral shaft morphology. Records also indicate that geographical and collection data were not available, and therefore, no consultation could be conducted. Thus, the human remains were classified as culturally unidentifiable.

On an unknown date, human remains representing a minimum of two individuals were removed from the Norton Site, Romeo, in Macomb County, MI. On an unknown date, the human remains were given to the museum (CIS reference #10123 and #10124). No known individuals were identified. No associated funerary objects are present.

According to museum records, the human remains are probably Native American. An assessment dated October 30, 1994, notes that, "one tooth which is not human, and a non-human long bone midshaft fragment" was intermingled with the human remains at the time the osteology review was conducted. It is unknown what was done with the non-human material. The Norton site is identified as Late Woodland Younge tradition based on "animal bones" and "fragments of pottery" as evidenced in "pits dug by the occupants." No other dating was performed at the Norton site; therefore no consultation could be conducted. Thus, the human remains were classified as culturally unidentifiable.

On an unknown date, human remains representing a minimum of four individuals were removed from the Drake Site, Farmington Hills, Oakland County, MI. In August 1977, the human remains were given to the museum by Charles Martinez and Rick Zurel, local archeologists, (CIS reference #10138). No known individuals were identified. The associated funerary object is one box of excavated material, which contains chert fragments, soil samples, and pottery fragments.

According to museum records, the human remains are Native American. According to Mr. Martinez, the Drake site falls into the early Younge Tradition or late Wayne ceramic tradition, which dates to approximately A.D. 700–800. Records indicate that there was a lack of information pertaining to linear descendants; therefore no consultation could be conducted by the museum. Thus, the human remains were classified as culturally unidentifiable.

The above-described human remains came to the museum through a variety of channels, but primarily as the result of construction work in southeastern Michigan over four decades prior to 1980. All have been identified as Native American based on skeletal morphology and/or archeological context. All have been determined to be culturally unidentifiable.

Officials of the Cranbrook Institute of Science have determined that, pursuant to 25 U.S.C. 3001(9), the human remains described above represent the physical remains of at least 39 individuals of Native American ancestry. Officials of the Cranbrook Institute of Science also have determined that, pursuant to 25 U.S.C. 3001(3)(A), the 34 objects described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the Cranbrook Institute of Science have determined that, pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and associated funerary objects and any present-day Indian tribe.

The Native American Graves Protection and Repatriation Review Committee (Review Committee) is responsible for recommending specific actions for disposition of culturally unidentifiable human remains. In April 2008, a request for the disposition of the Native American human remains was officially submitted to the Cranbrook Institute of Science by the Little Traverse Bay Bands of the Odawa Indians on behalf of the Michigan Anishnaabek Cultural Preservation and Repatriation Alliance (MACPRA), a non-federally recognized Indian group, whose members are the following Federally-recognized Indian tribes: Bay Mills Indian Community, Michigan; Grand Traverse Band of Ottawa and Chippewa Indians, Michigan; Keweenaw Bay Indian Community, Michigan; Lac Vieux Desert Band of Lake Superior Chippewa Indians, Michigan; Little River Band of Ottawa

Indians, Michigan; Little Traverse Bay Bands of Odawa Indians, Michigan; Nottawaseppi Huron Band of the Potawatomi, Michigan; Pokagon Band of Potawatomi Indians, Michigan and Indiana; Saginaw Chippewa Indian Tribe of Michigan; and Sault Ste. Marie Tribe of Chippewa Indians of Michigan. These Indian tribes are considered to be the Anishnaabek People of the Great Lakes region.

On July 30, 2008, the Cranbrook Institute requested that the Review Committee recommend disposition of 60 culturally unidentifiable human remains to the Indian tribes, as aboriginal occupants of Michigan. The Review Committee considered the proposal at its October 11–12, 2008, meeting and recommended disposition of the human remains to the Indian tribes listed above, as they are considered to be the Anishnaabek People of the Great Lakes region, and the aboriginal occupants of the area currently referenced as Michigan.

An April 3, 2009, letter from the Designated Federal Officer, writing on behalf of the Secretary of the Interior, transmitted the authorization for the museum to effect disposition of the physical remains of 39 of the 60 culturally unidentifiable individuals contingent on the publication of a Notice of Inventory Completion in the **Federal Register**. This notice fulfills that requirement. In the same letter, the Secretary recommended the transfer of the associated funerary objects to the Indian tribes listed above to the extent allowed by Federal, state, or local law.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains and/or associated funerary objects should contact Michael Stafford, PhD., Director, Cranbrook Institute of Science, PO Box 801, Bloomfield Hills, MI 48303, telephone (248) 645–3204, before July 26, 2010. Disposition of the human remains and associated funerary objects to the Bay Mills Indian Community, Michigan; Grand Traverse Band of Ottawa and Chippewa Indians, Michigan; Keweenaw Bay Indian Community, Michigan; Lac Vieux Desert Band of Lake Superior Chippewa Indians, Michigan; Little River Band of Ottawa Indians, Michigan; Little Traverse Bay Bands of Odawa Indians, Michigan; Nottawaseppi Huron Band of the Potawatomi, Michigan; Pokagon Band of Potawatomi Indians, Michigan and Indiana; Saginaw Chippewa Indian Tribe of Michigan; and Sault Ste. Marie Tribe of Chippewa Indians of Michigan, may proceed after that date if no additional claimants come forward.

The Cranbrook Institute of Science is responsible for notifying the Bay Mills Indian Community, Michigan; Grand Traverse Band of Ottawa and Chippewa Indians, Michigan; Keweenaw Bay Indian Community, Michigan; Lac Vieux Desert Band of Lake Superior Chippewa Indians, Michigan; Little River Band of Ottawa Indians, Michigan; Little Traverse Bay Bands of Odawa Indians, Michigan; Nottawaseppi Huron Band of the Potawatomi, Michigan; Pokagon Band of Potawatomi Indians, Michigan and Indiana; Saginaw Chippewa Indian Tribe of Michigan; and Sault Ste. Marie Tribe of Chippewa Indians of Michigan that this notice has been published.

Dated: June 18, 2010

David Tarler,

Acting Manager, National NAGPRA Program.

[FR Doc. 2010–15335 Filed 6–23–10; 8:45 am]

BILLING CODE 4312–50–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion: U.S. Department of Defense, Army Corps of Engineers, Walla Walla District, Walla Walla, WA and Museum of Anthropology, Washington State University, Pullman, WA

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects in the control of the U.S. Department of Defense, Army Corps of Engineers, Walla Walla District, Walla Walla, WA, and in the physical custody of the Museum of Anthropology, Washington State University, Pullman, WA. The human remains and associated funerary objects were removed from Columbia, Franklin, Garfield, and Whitman Counties, WA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

A detailed assessment of the human remains was made by U.S. Department of Defense, Army Corps of Engineers professional staff in consultation with representatives of Confederated Tribes of the Colville Reservation, Washington; Confederated Tribes of the Umatilla Indian Reservation, Oregon; Confederated Tribes of the Warm Springs Reservation of Oregon; Confederated Tribes and Bands of the Yakama Nation, Washington; Nez Perce Tribe, Idaho; and the Wanapum Band, a non-federally recognized Indian group.

In 1965, human remains representing a minimum of one individual were removed from the village portion of site 45CO1 near the mouth of the Tucannon River, Columbia County, WA. The excavation was conducted on Army Corps of Engineers land under contract with the National Park Service. No burials were reported during the excavations. In 1996, Washington State University unexpectedly encountered human remains in level bags containing unprovenienced materials collected from the surface of site 45CO1. No known individual was identified. No associated funerary objects are present.

This individual was determined to be Native American based on significant tooth wear and the types of artifacts removed during the excavation, including projectile points, scrapers, antler tine tools, utilized flakes, and awls, which are tool types common in the Plateau culture area. Site 45CO1 is adjacent to Cayuse, Nez Perce, and Palus Indian lands judicially established in 1978.

In 1958 and 1959, human remains representing a minimum of 14 individuals were removed from Fishhook Island Site, 45FR42, Franklin County, WA. In 1958, the Columbia Archaeological Society excavated at Fishhook Island. In 1959, the Washington State University excavated at Fishhook Island while under contract with the National Park Service. The 1958 and 1959 excavations took place before the land was acquired by the Army Corps of Engineers. At an unknown date, the human remains excavated were delivered to Washington State University and University of Idaho. In 2000, the University of Idaho transferred the 45FR42 materials to Washington State University. In 2006, the Army Corps of Engineers' physical anthropologists inventoried the human remains. Some of the human remains collected are not currently in the museum collection, and may have been reburied in 1991. Burials numbers 1 through 21 were consecutively assigned by the Columbia Archaeological Society to their burial excavations. Washington State University assigned burial numbers 1 through 24 to their burial excavations. The duplicate burial

numbers and scant records do not, in many instances, permit clear association of funerary objects with the burials removed. No known individuals were identified. The 351 associated funerary objects are 102 counted objects and 249 lots of objects. The 102 counted objects are 9 adzes, 5 bifaces, 9 bone awls, 2 bone tool fragments, 3 bone wedges, 2 combs, 1 composite harpoon, 2 copper pendants, 13 cores, 1 digging stick handle, 5 drills, 1 grooved cobble, 1 hafted beaver tooth chisel, 1 hammerstone, 1 jadite club, 1 metal bracelet, 1 pestle, 2 preforms, 32 projectile points, 4 scrapers, 2 cobble spalls, 2 stone abraders, 1 stone pendant, and 1 thimble. The 249 lots of objects are 4 lots of animal hair, 17 lots of animal remains, 26 lots of bag residue, 18 lots of modified bone fragments, 2 lots of charcoal, 1 lot of cordage, 7 lots of elk tooth beads, 2 lots of fabric remains, 1 lot of fire cracked rock, 81 lots of flakes, 8 lots of glass and metal beads, 7 lots of juniper seed beads, 2 lots of leather fragments, 4 lots of matting, 5 lots of metal fragments, 2 lots of nails, 6 lots of plant remains, 4 lots of red ochre, 35 lots of shell beads, 4 lots of shell pendant fragments, 4 lots of shell remains, and 9 lots of wood fragments.

The 45FR42 burials are estimated to range from the proto-historic/historic time periods to the early 1920s. In the early 1900s, local residents witnessed Native American burial ceremonies held on Fishhook Island, and remember Cayuse, Walla Walla, Wallula, and Palus people in the general area during the late 1880s and early 1900s. Fishhook Island is located within the overlapping 19th century territories of the Palus and Walla Walla people.

In 1959, human remains representing a minimum of two individuals were removed from the Klundt or Page Site, 45FR43, Franklin County, WA. Washington State University excavated three housepits at 45FR43 on Army Corps of Engineers project lands while under contract with the National Park Service. The resultant collection was curated at Washington State University, but was not formally reported. In 1992, Washington State University unexpectedly encountered human remains listed in collection records. In 2006, Army Corps of Engineers physical anthropologists inventoried the human remains. No known individuals were identified. The four associated funerary objects are one counted object and three lots of objects, which are one ceramic bead, one lot of fire cracked rock, one lot of charcoal, and one lot of bag residue.

The human remains were associated with a prehistoric housepit village and Native American artifacts dating to the Harder Phase (2500 BP to 1000 BP). Early and late ethnographic documentation indicates the present-day location of 45FR43 is within the overlapping 19th century territories of the Cayuse, Palus, and Walla Walla people.

In 1959, 1960, or 1961, human remains representing a minimum of three individuals were removed from the Windust Caves Site, 45FR46, Franklin County, WA. Washington State University excavated in three of the nine caves in this complex while under contract with the National Park Service. A lined storage pit feature was encountered in Cave C, but no burials were reported during the excavations. Unknown collectors dug in Cave C between Washington State University's field seasons. In 1997, Washington State University unexpectedly found human remains in an unsorted Cave C level bag containing material from a collector's back dirt pile. No known individuals were identified. The 84 associated funerary objects are 9 counted objects and 75 lots of objects. The nine counted objects are three bifaces, four cores, and two projectile points. The 75 lots of objects are 4 lots of animal remains, 9 lots of bag residue, 2 lots of bird remains, 1 lot of bullet cartridge fragments, 1 lot of can fragments, 4 lots of charcoal, 2 lots of cordage, 1 lot of fabric remains, 24 lots of flakes, 2 lots of glass fragments, 2 lots of metal fragments, 3 lots of modified wood, 1 lot of nails, 5 lots of paper fragments, 6 lots of plant remains, 4 lots of shell remains, and 4 lots of wood fragments.

Information is limited making it impossible to determine the age of the remains. However, Native American materials and features associated with the late prehistoric period are present, including preserved Native American cordage and wood artifacts. Early and late ethnographic documentation indicates the present-day location of 45FR46 is within the overlapping 19th century territories of the Palus and Walla Walla people.

In 1960, human remains representing a minimum of two individuals were removed from the Ford Island Site, 45FR47, Franklin County, WA. Washington State University excavated at 45FR47 while under contract with the Army Corps of Engineers. The remains were delivered to the University of Idaho and Washington State University and are thought to have been reburied before 1985. In 1992, a Washington State University inventory recorded the presence of Burial 6 materials in the collection. Between 1996 and 2000, the University of Idaho transferred materials to Washington State University. In 2003, the transferred materials were inventoried, and the presence of Burial 9 materials was recorded along with funerary objects from other 45FR47 burials. No known individuals were identified. The 168 associated funerary objects are 6 counted objects and 162 lots of objects. The six counted objects are one core, two unidentified ground stone items, one iron container, and two shell ornaments. The 162 lots of objects are 1 lot of animal remains, 10 lots of bag residue, 1 lot of buttons, 17 lots of fabric remains, 1 lot of feathers, 6 lots of flakes, 2 lots of leather fragments, 3 lots of metal beads, 2 lots of organic items, 1 lot of red ochre, 4 lots of shell beads, 98 lots of trade beads, 1 lot of unidentified glass items, 13 lots of unidentified metal items, and 2 lots of wood fragments.

The burials associated with the 45FR47 collection are Native American as demonstrated by the presence of Native American Plateau objects, Plateau burial patterns, and eyewitness accounts of Native Americans living on Ford Island in the 1900s. Dentalia shell beads start to be common in the Plateau archeological record about 3,000 years ago. Glass beads became available to Indian groups from the 1780s through the 1810s. Early and late ethnographic documentation indicates the island is located within the overlapping 19th century territories of the Palus and Walla Walla people.

In 1981, human remains representing a minimum of one individual were removed from the Lyon's Fish Hatchery/Trestle City/Joso Site, 45FR51, Franklin County, WA. The Lyons Ferry Fish Hatchery Project was proposed for construction in the area of 45FR51 during the late 1970s. An archeological survey and test excavations were conducted prior to project initiation. No burials were reported during the archeological investigations; however, a canoe burial was unexpectedly encountered during hatchery construction. The burial was removed and delivered to the University of Idaho under contract with the Army Corps of Engineers. In 2000, the University of Idaho transferred the materials to Washington State University. No known individual was identified. The 15 lots of associated funerary objects are 3 lots of animal remains, 1 lot of fabric remains, 6 lots of leather fragments, 1 lot of metal fragments, 2 lots of plant remains, 1 lot of sediment, and 1 lot of shell remains.

The use of canoes in a burial setting is consistent with the Native American Plateau cultural area. The age of the

burial is estimated to range from 1820 to 1850. Site 45FR51 is within judicially established Palus Indian land, and north of the judicially established Cayuse and Nez Perce Indian lands.

In 1977, human remains representing a minimum of two individuals were removed from the Kelly Bar Site, 45GA37, Garfield County, WA. The remains were found within slumped sediments and appeared to lie within a redeposited Mt. Mazama ash layer. The human remains were removed by the University of Idaho under contract with the Army Corps of Engineers. Following removal, the remains were delivered to the University of Idaho. In 2000, the University of Idaho transferred the remains to Washington State University. In 2003, Washington State University inventoried the human remains of an adult and a child. There are no records regarding the collection of a second burial. These individuals were determined to be Native American based on artifacts observed at site 45GA37 which are common in the Plateau culture area. No known individuals were identified. No associated funerary objects are present.

In 1966, human remains representing a minimum of one individual were removed from site 45GA53, Garfield County, WA. The human remains are unprovenienced and were collected from the surface of the site during the Lower Granite/Little Goose Survey and delivered to the University of Idaho prior to land acquisition by the Army Corps of Engineers. Between 1996 and 1998, the human remains were transferred to Washington State University. In 2006, Army Corps of Engineers physical anthropologists inventoried the remains. No known individual was identified. No associated funerary objects are present.

The individual is determined to be Native American due to burial cairns and artifacts at 45GA53, which are consistent with the Plateau culture area. Site 45GA53 is adjacent to judicially established Nez Perce lands and within the overlapping 19th century territories of the Nez Perce and Palus people.

In 1970, human remains representing a minimum of two individuals were removed during excavation of Housepit 7, 45GA61, Garfield County, WA. The burials were removed from Army Corps of Engineers land by Washington State University while under contract with the National Park Service. Following removal, the burials were delivered to the University of Idaho and Washington State University. In 2000, the University of Idaho transferred human remains and funerary objects to Washington State University. No known individuals were identified. The eight associated funerary objects are one counted object and seven lots of objects, which are one piece of modified bone, four lots of flakes, one lot of red ochre, one lot of shell remains, and one lot of animal remains.

The burials, the housepit, and the presence of Native American tools and materials are consistent with Plateau culture area customs and characteristics. Early and late ethnographic documentation indicates that the present-day locations are within overlapping 19th century territories of the Palus and Nez Perce people.

In 1981, 1982 or 1989, human remains representing a minimum of one individual were removed from beach lag deposits at the Riparia Site, 45WT1, Whitman County, WA. The partial remains were removed by Washington State University while under contract with the Army Corps of Engineers. Following removal, the human remains were delivered to Washington State University. No known individual was identified. No associated funerary objects are present.

The archeological assemblage associated with the 45WT1 beach lag deposits is consistent with the Native American Plateau culture area. The Riparia Site is located within the 19th century Palus territory, north of the 19th century Walla Walla territory, and west of the 19th century Nez Perce territory.

In 1963, human remains representing a minimum of one individual were removed from 45WT2, Whitman County, WA. Washington State University excavated three disturbed burials and Burial 1 while under contract with the National Park Service and prior to land acquisition by the Army Corps of Engineers. Following removal, the human remains and funerary objects were delivered to Washington State University. No known individual was identified. The three associated funerary objects are one counted object and two lots of objects, which are one hammerstone, one lot of shell beads, and one lot of stones.

The historic period burial pattern is consistent with the cultural traditions of the Palus Indians who occupied the Palouse River drainage during historic times. Site 45WT2 is located at the mouth of the Palouse River and is within judicially established Palus Indian land, and north and northwest of judicially established Cayuse and Nez Perce Indian lands.

In 1965, human remains representing a minimum of one individual were removed from the Lower Granite Dam Site, 45WT35, Whitman County, WA. The partial human remains were removed by Washington State University while under contract with the National Park Service and prior to land acquisition by the Army Corps of Engineers. Following removal, the remains were delivered to Washington State University. In 1992, Washington State University identified one human molar in the collection. No known individual was identified. No associated funerary objects are present.

The site is described as a prehistoric village that included no reports of burials. This individual was determined to be Native American based on significant tooth wear and the types of artifacts present in the collection, which are common in the Plateau culture area. Early and late ethnographic documentation indicates site 45WT35 is within the overlapping 19th century territory of the Palus and Nez Perce people.

In 1977 or 1978, human remains representing a minimum of one individual were removed from the Blyton Landing Burial Site, 45WT53, Whitman County, WA. The University of Idaho removed burials from this location while under contract with the Army Corps of Engineers as part of the Army Corps of Engineers' Nez Perce Grave Recovery Project. The human remains were reburied at Spalding, ID, in 1978. In 1987, Washington State University students observed a human bone fragment at Blyton Landing and delivered it to Washington State University. In 2000, the University of Idaho transferred a portion of the 45WT53 collection to Washington State University. In 2003, Washington State University inventoried the transferred materials, and identified funerary objects associated with the reburied Burials 1 through 5 and surface-collected human remains from an unknown burial, and these unassociated funerary objects are in a companion Notice of Intent to Repatriate Cultural Items. The only human remains remaining in the collection are from the removal in 1987. No known individual was identified. No associated funerary objects are present.

The human remains from Burials 1 through 5 and the unknown burial are determined to be Native American, as was previously determined during the Nez Perce Grave Recovery Project. Site 45WT53 is adjacent to judicially established Nez Perce Indian lands and east of judicially established Palus Indian lands.

In 1967, human remains representing a minimum of five individuals were removed from the Ferguson Burial Site, 45WT55, Whitman County, WA. The Washington State University field school excavated Burials 1 through 7

prior to land acquisition by the Army Corps of Engineers. The burials were delivered to Washington State University following removal. At an unknown time, the human remains were transferred to the University of Idaho where a pre-NAGPRA program of repatriation was ongoing. In 2000, the University of Idaho transferred the collection to Washington State University. In 2006, the human remains were inventoried and Burials 1, 3, 4, 5, and 6 were found in the collection. No known individuals were identified. The seven associated funerary objects are one counted object and six lots of objects, which are one pestle, one lot of animal remains, one lot of basketry fragments, and four lots of wood fragments.

The individuals are determined to be Native American based on dental characteristics, significant tooth wear, and archeological burial patterns which are age diagnostic attributes of the late prehistoric period on the southern Columbia Plateau. Site 45WT55 is adjacent to judicially established Nez Perce Indian land and within the overlapping 19th century territories of the Palus and Nez Perce people.

In 1971, human remains representing a minimum of one individual were removed from the Lawyer Burial Site, 45WT101, Whitman County, WA. This individual is 1 of 33 burials removed by the University of Idaho while under contract to the Army Corps of Engineers as part of the Nez Perce Grave Removal Project. The 45WT101 burials were reported as reburied at Spalding, ID, in 1978. In 1998 and 2000, the University of Idaho transferred the 45WT101 collection to Washington State University. In 2001, Washington State University encountered human remains associated with Burial 21 during a collections assessment inventory. The individual was previously determined to be Nez Perce as part of the Nez Perce Grave Removal Project. No known individual was identified. The two associated funerary objects are projectile points.

In 1973, human remains representing a minimum of one individual were removed from the Wilma Bar Culvert Burial Site, 45WT103, Whitman County, WA. This individual is one of nine burials removed by the University of Idaho while under contract to the Army Corps of Engineers as part of the Nez Perce Grave Removal Project. Following removal, the burials were delivered to the University of Idaho. The 45WT103 burials were reported as reburied at Spalding, ID, in 1978. The collection was transferred to Washington State University at an unknown date. In 2003, Washington State University encountered partial human remains from Burial 7 during a collections inventory. The individual was previously determined to be Nez Perce during initiation and completion of the Nez Perce Grave Removal Project. No known individual was identified. No associated funerary objects are present.

Evidence supports cultural affiliation of the Confederated Tribes of the Colville Reservation, Confederated Tribes of the Umatilla Indian Reservation, Confederated Tribes of the Warm Springs Indian Reservation of Oregon, Confederated Tribes and Bands of the Yakama Nation, and the Nez Perce Tribe with the above-mentioned sites and collections. Additionally, a cultural relationship is determined to exist between the sites and collections and the Wanapum Band, a non-federally recognized Indian group. Other relevant information provided by Indian tribes and the Wanapum Band indicates they are direct descendant communities from the Native people that jointly used the areas, are intermarried, have enrolled members with documented connections to ancestors buried along the Snake River, and are all part of the more broadly defined Plateau cultural community.

Officials of the U.S. Department of Defense, Army Corps of Engineers, Walla Walla District, have determined that, pursuant to 25 U.S.C. 3001(9), the human remains described above represent the physical remains of 39 individuals of Native American ancestry. Officials of the U.S. Department of Defense, Army Corps of Engineers, Walla Walla District, also have determined that, pursuant to 25 U.S.C. 3001(3)(A), the 642 objects described above, which are 123 counted objects and 519 lots of objects, are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Further, officials of the U.S. Department of Defense, Army Corps of Engineers, Walla Walla District, have determined that, pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Confederated Tribes of the Colville Reservation, Washington; Confederated Tribes of the Umatilla Indian Reservation, Oregon; Confederated Tribes of the Warm Springs Indian Reservation of Oregon; Confederated Tribes and Bands of the Yakama Nation, Washington; and the Nez Perce Tribe, Idaho. Lastly, officials of the U.S. Department of Defense, Army Corps of Engineers, Walla Walla District, have determined that there is a cultural relationship between the Native American human remains and associated funerary objects and the Wanapum Band, a non-federally recognized Indian group.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary objects should contact LTC Michael Farrell, U.S. Department of Defense, Army Corps of Engineers, Walla Walla District, 201 North Third Ave., Walla Walla, WA 99362, telephone (509) 527–7700, before July 26, 2010. Repatriation of the human remains and associated funerary objects to the Confederated Tribes of the Colville Reservation, Washington; Confederated Tribes of the Umatilla Indian Reservation, Oregon; Confederated Tribes of the Warm Springs Indian Reservation of Oregon; Confederated Tribes and Bands of the Yakama Nation, Washington; and the Nez Perce Tribe, Idaho, may proceed after that date if no additional claimants come forward. The U.S. Department of Defense, Army Corps of Engineers, Walla Walla District, acknowledges the participation of the Wanapum Band, a non-federally recognized Indian group, in the transfer of the human remains and associated funerary objects to the Indian tribes.

The U.S. Department of Defense, Army Corps of Engineers, Walla Walla District, is responsible for notifying the Confederated Tribes of the Colville Reservation, Washington; Confederated Tribes of the Umatilla Indian Reservation, Oregon; Confederated Tribes of the Warm Springs Indian Reservation of Oregon; Confederated Tribes and Bands of the Yakama Nation, Washington; Nez Perce Tribe, Idaho; and the Wanapum Band, a non-federally recognized Indian group, that this notice has been published.

Dated: June 18, 2010

David Tarler,

Acting Manager, National NAGPRA Program.

[FR Doc. 2010–15325 Filed 6–23–10; 8:45 am]

BILLING CODE 4312–50–S

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

No Child Left Behind School Facilities and Construction Negotiated Rulemaking Committee—Notice of Meeting

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Bureau of Indian Affairs is announcing that the No Child Left Behind School Facilities and Construction Negotiated Rulemaking Committee will hold its third meeting in Rapid City, South Dakota. The purpose of the meeting is to continue working on reports and recommendations to Congress and the Secretary as required under the No Child Left Behind Act of 2001.

DATES: The Committee's third meeting will begin at 8:30 a.m. on July 12, 2010, and end at 5 p.m. on July 15, 2010.

ADDRESSES: The meeting will be held at the Rushmore Plaza Holiday Inn, 505 North Fifth Street, Rapid City, South Dakota 57709.

FOR FURTHER INFORMATION CONTACT: The Designated Federal Official, Michele F. Singer, Director, Office of Regulatory Affairs and Collaborative Action, Office of the Assistant Secretary—Indian Affairs, 1001 Indian School Road, NW., Suite 312, Albuquerque, NM 87104; telephone (505) 563–3805; fax (505) 563–3811.

SUPPLEMENTARY INFORMATION: The No Child Left Behind School Facilities and Construction Negotiated Rulemaking Committee was established to prepare and submit to the Secretary a catalog of the conditions at Bureau-funded schools, and to prepare reports covering: The school replacement and new construction needs at Bureau-funded school facilities; a formula for the equitable distribution of funds to address those needs; a list of major and minor renovation needs at those facilities; and a formula for equitable distribution of funds to address those needs. The reports are to be submitted to the Secretary and to Congress. The Committee also expects to draft proposed regulations covering construction standards for heating, lighting, and cooling in home-living (dormitory) situations.

The following items will be on the agenda:

- Review and approve April 2010 meeting summary;
- Review of April 2010 action items;
- Discussion on report outline;
- Discussion of Committee caucusing and outreach procedures and identifying any upcoming outreach opportunities;
- Updates from and discussion on: The Dormitory Standards Subcommittee, Catalog/Inventory Subcommittee, Formula for Repair and Renovation Subcommittee, and the Education Subcommittee;
- Bureau of Indian Education briefing on Native American Student Information System;
- Small group and subcommittee work: Dormitory Standards, Catalog/Inventory, Formula for Repair and Renovation, and Education;
- Report back from subcommittee work and discussion;
- School visit to Wounded Knee District School and Loneman Day School;
- Reflections on the school visit;
- Brief update on school facilities FY11 budget;
- Review any language drafted by Committee members concurrent with school visit;
- Review third meeting discussions; and
- Public comments.

Written comments may be sent to the Designated Federal Official listed in the **FOR FURTHER INFORMATION CONTACT** section above. All meetings are open to the public; however, transportation, lodging, and meals are the responsibility of the participating public.

Dated: June 18, 2010.

Donald Laverdure,

Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 2010–15261 Filed 6–23–10; 8:45 am]

BILLING CODE 4310–W7–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCA930000, L14300000.ER0000; CACA 7059, CACA 7060, CACA 7101, CACA 7102, and CACA 7239]

Public Land Order No. 7743; Partial Revocation of Five Secretarial Orders for Reclamation Project Purposes on the Colorado River, California.

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order partially revokes five Secretarial Orders insofar as they affect 2,865.86 acres of public lands previously withdrawn for reclamation project purposes on the Colorado River. The lands are no longer needed for reclamation purposes and the Bureau of Reclamation has relinquished the lands accordingly. This order opens the lands to the Act of Congress dated January 12, 1891, as amended by the Act of Congress dated March 1, 1907, to facilitate the issuance of a trust patent to the Chemehuevi Indian Tribe. The lands will remain withdrawn from all forms of settlement and entry under the terms of an Order of the Secretary of the Interior dated February 2, 1907.

DATES: *Effective Date:* June 24, 2010.

FOR FURTHER INFORMATION CONTACT: Duane Marti, Realty Specialist, at 916–978–4675 or via e-mail at *Duane_Marti@ca.blm.gov.*

SUPPLEMENTARY INFORMATION: The Bureau of Reclamation has determined that the lands are no longer needed for reclamation purposes as previously withdrawn and has requested the partial revocation. These lands are included in an overlapping reservation on behalf of the Chemehuevi Indian Tribe, therefore the lands will remain withdrawn from all forms of settlement and entry. The Bureau of Indian Affairs has requested that the Bureau of Land Management issue a trust patent for the Chemehuevi Indian Tribe's reservation along the Colorado River in San Bernardino County. The lands are being opened to the Act of Congress dated January 12, 1891 (26 Stat. 712), as amended by the Act of Congress dated March 1, 1907 (34 Stat. 1015, 1022), to facilitate the issuance of the trust patent.

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714, it is ordered as follows:

1. The Secretarial Orders dated July 2, 1902 (as modified by the Secretarial Order dated August 26, 1902), April 14, 1903, September 8, 1903, June 4, 1930, and October 16, 1931, respectively, which withdrew public lands for Colorado River Surveys and reclamation project purposes (including Colorado River Surveys and a "Colorado River Project"), are hereby revoked insofar as they affect the following described lands:

San Bernardino Meridian

T. 6 N., R. 24 E.,
  Sec. 35.
T. 4 N., R. 25 E.,
  Sec. 25, lots 1 and 2, W½ NE¼, NW¼, and S½.
T. 4 N., R. 26 E.,
  Sec. 19, lots 1, 2, and 3;
  Sec. 29, lots 1 and 2;
  Sec. 30, lots 1 to 20, inclusive;
  Sec. 31, lots 1 to 10, inclusive, S½ NE¼, and SE¼;
  Sec. 32, lots 1 to 9, inclusive, SW¼ NE¼, and S½;
  Sec. 33, lots 1 to 8, inclusive, and SW¼ SW¼.

The areas described aggregate 2,865.86 acres in San Bernardino County.

2. At 10 a.m. on June 24, 2010, the lands described in Paragraph 1 will be opened to the provisions of the Act of Congress dated January 12, 1891 (26 Stat. 712), as amended by the Act of Congress dated March 1, 1907 (34 Stat.

1015, 1022), generally, subject to valid existing rights, the provisions of existing withdrawals (including, but not limited to, the withdrawal made by Secretarial Order dated February 2, 1907), other segregations of record, and the requirements of applicable law.

Dated: June 16, 2010.

Wilma A. Lewis,

Assistant Secretary—Land and Minerals Management.

[FR Doc. 2010–15382 Filed 6–22–10; 11:15 am]

BILLING CODE 4310–MN–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–666]

In the Matter of Certain Cold Cathode Fluorescent Lamp ("CCFL") Inverter Circuits and Products Containing the Same; Notice of Commission Final Determination of No Violation of Section 337; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review portions of the final initial determination ("ID") issued by the presiding administrative law judge ("ALJ") on April 19, 2010, and to affirm the final ID's finding of no violation of section 337 on modified grounds. The above-captioned investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Daniel E. Valencia, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–1999. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on January 14, 2009, based on a complaint filed by O2 Micro International, Ltd. of the Cayman Islands and O2 Micro, Inc. of Santa Clara, California. 74 FR 2099. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain cold cathode fluorescent lamp inverter circuits and products containing the same by reason of infringement of various U.S. patents. The complaint names ten respondents, including Monolithic Power Systems Inc. of San Jose, California ("MPS"); Microsemi Corporation of Irvine, California ("Microsemi"); ASUSTeK Computer Inc. of Taipei, Taiwan and ASUS Computer International America of Fremont, California (collectively, "ASUS").

On April 19, 2010, the ALJ issued his final ID finding no violation of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of CCFL inverter circuits and products containing the same by reason of infringement of U.S. Patent 7,417,382 ("the '382 patent"). The Commission investigative attorney ("IA"), complainant O2 Micro, respondents MPS and ASUS, and respondent Microsemi each filed petitions for review of the ID on May 3, 2010. The IA, O2 Micro, respondents MPS and ASUS, and respondent Microsemi each filed responses to the petitions for review on May 11, 2010.

Having examined the record of this investigation, including the ALJ's final ID, the petitions for review, and the responses thereto, the Commission has determined to review the final ID in part. In particular, the Commission has determined to review (1) the ID's findings that the LX1691 and LX1693 Microsemi products infringe the asserted claims of the '382 patent, and (2) the ID's finding that O2 Micro has not satisfied the domestic industry requirement.

Upon review, the Commission has determined to (1) reverse the ALJ's findings that the LX1691 and LX1693 Microsemi products infringe the asserted claims of the '382 patent, and (2) reverse the ALJ's determination that O2 Micro has not satisfied the domestic industry requirement. The Commission has determined that neither MPS, ASUS, nor Microsemi have violated section 337, and has terminated the investigation. A Commission opinion will issue shortly.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in sections 210.42–50 of the Commission's Rules of Practice and Procedure (19 CFR 210.42–50).

Issued: June 18, 2010.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 2010–15266 Filed 6–23–10; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–10–022]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: June 30, 2010 at 10 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED

1. Agenda for future meetings: none.
2. Minutes.
3. Ratification list.
4. Inv. Nos. 701–TA–473 and 731–TA–1173 (Final) (Certain Potassium Phosphate Salts from China)—briefing and vote. (The Commission is currently scheduled to transmit its determinations and Commissioners' opinions to the Secretary of Commerce on or before July 13, 2010.)
5. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: June 22, 2010.

By order of the Commission:

William R. Bishop,

Hearings and Meetings Coordinator.

[FR Doc. 2010–15521 Filed 6–22–10; 4:15 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Proposed Information Collection Request Submitted for Public Comment and Recommendations; Program To Prevent Smoking Underground and in Hazardous Surface Areas (Pertains to Underground Coal Mines)

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments concerning the extension of the information collection related to the 30 CFR 75.1702 and 75.1702–1.

DATES: All comments must be received by midnight Eastern Daylight Savings Time on August 23, 2010.

ADDRESSES: Comments must clearly be identified with the rule title and may be submitted to MSHA by any of the following methods:

(1) *Electronic mail: zzMSH-Comments@dol.gov.*

(2) *Facsimile:* (202) 693–9441.

(3) *Regular Mail:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2350, Arlington, VA 22209–3939.

(4) *Hand Delivery or Courier:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2350, Arlington, VA 22209–3939. Sign in at the receptionist's desk on the 21st floor.

FOR FURTHER INFORMATION CONTACT: Mario Distasio, Chief of the Economic Analysis Division, Office of Standards, Regulations, and Variances, MSHA, at *distasio.mario@dol.gov* (e-mail), 202–693–9445 (voicemail), 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Section 317(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act), 30 U.S.C. 877(c), and 30 CFR 75.1702 prohibit persons from smoking or carrying smoking materials underground or in places where there is a fire or explosion hazard. Under the Mine Act and § 75.1702, coal mine operators are required to develop programs to prevent persons from carrying smoking materials, matches, or lighters underground and to prevent smoking in hazardous areas, such as in or around oil houses, explosives magazines, etc. Section 75.1702–1 requires that the mine operator submit the program for searching miners for smoking materials to MSHA for approval. The purpose of the program is to ensure that a fire or explosion hazard does not occur. Section 103(h) of the Mine Act, 30 U.S.C. 813, authorizes MSHA to collect information necessary to carry out its duty in protecting the safety and health of miners.

II. Desired Focus of Comments

MSHA is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

A copy of the proposed information collection request can be obtained by contacting the employee listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, or viewed on the Internet by selecting "Rules & Reg", and then selecting "FedReg.Docs". On the next screen, select "Paperwork Reduction Act Supporting Statement" to view documents supporting the **Federal Register** Notice.

III. Current Actions

This request for collection of information contains notification and recordkeeping provisions for 30 CFR 75.1702 and 75.1702–1 Safety Standards for Underground Coal Mines-Smoking, Prohibition and Smoking Programs. While there is no specific requirement that records be maintained for more than three years, all underground coal mines must have an approved program for searching miners for smoking materials in effect during the entire time they are operating. MSHA requires this program as one of the preliminary plans which must be submitted for approval in accordance with 30 CFR 75.1721(b)(9) prior to commencing the extraction of coal (30 CFR 75.1721—Opening of new underground coal mines, or reopening and reactivating of abandoned or deactivated coal mines, notification by the operator; requirements). Once submitted and approved, revisions to the revised approved plan is only required where the mine ownership changes or the smoker search plan proves to be inadequate to prevent the carrying of smoking articles underground. This collection of information is otherwise consistent with the guidelines in 5 CFR 1320.5. MSHA does not intend to publish the results of this information collection and there are no forms associated with this information collection on which to display the OMB number and expiration date.

There are no certification exceptions identified with this information collection and the collection of this information does not employ statistical methods.

Type of Review: Extension.

Agency: Mine Safety and Health Administration.

OMB Number: 1219–0041.

Frequency: On Occasion.

Affected Public: Business or other for-profit.

Cost to Federal Government: $2,425.68.

Total Burden Respondents: 144.

Total Number of Responses: 144.

Total Burden Hours: 72.

Total Hour Burden Cost (operating/maintaining): $6,098.40

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated June 18, 2010.

Patricia W. Silvey,

Director, Office of Standards, and Regulations, and Variances.

[FR Doc. 2010–15269 Filed 6–23–10; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Proposed Information Collection Request Submitted for Public Comment and Recommendations; Safety Standards for Underground Coal Mine Ventilation—Belt Entry Used as an Intake Air Course To Ventilate Working Sections and Areas Where Mechanized Mining Equipment Is Being Installed or Removed

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments concerning the extension of the information collection related to the 30 CFR 75.350, 75.351, 75.352, 75.371.

DATES: All comments must be received by midnight Eastern Daylight Savings Time on August 23, 2010.

ADDRESSES: Comments must clearly be identified with the rule title and may be submitted to MSHA by any of the following methods:

(1) *Electronic mail: zzMSHA-Comments@dol.gov.*

(2) *Facsimile:* (202) 693–9441.

(3) *Regular Mail:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2350, Arlington, VA 22209–3939.

(4) *Hand Delivery or Courier:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2350, Arlington, VA 22209–3939. Sign in at the receptionist's desk on the 21st floor.

FOR FURTHER INFORMATION CONTACT: Mario Distasio, Chief of the Economic Analysis Division, Office of Standards, Regulations, and Variances, MSHA, at *distasio.mario@dol.gov* (e-mail), 202–693–9445 (voicemail), 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

The Safety Standards for Underground Coal Mine Ventilation Belt Entry rule provides safety requirements for the use of the conveyor belt entry as a ventilation intake to course fresh air to working sections and areas where mechanized mining equipment is being installed or removed in mines with three or more entries. This rule establishes additional protective provisions that mine operators must follow if they want to use belt air to ventilate working sections.

- 75.351(b)(3) requires posting at the surface location of an up-to-date map or schematic showing air flow directions and the location and type of all Atmospheric Monitoring System (AMS) sensors.
- 75.351(n)(1) requires that sensors used to detect CO or smoke be visually examined at least once each shift, when belts are operated as part of a production shift. If hazardous conditions are found during the visual exam, then a log of such conditions must be filed under existing section 75.363(b)—Hazardous conditions; posting, correcting and recording (OMB approval 1219–0088).
- 75.351(n)(2) and 75.351(n)(3) require that alarms for AMS be tested every seven days and that CO, smoke, or methane sensors be calibrated, every 31 days respectively.
- 75.351(o)(1)(i) requires that a record be made if the AMS emits an alert or alarm signal.
- 75.351(o)(1)(ii) requires that, if a malfunction in the system occurs, a record be made of the malfunction and the corrective action to return the system to proper operating condition.
- 75.351(o)(1)(iii) requires that the persons doing the weekly test of alert and alarm signals, the monthly calibration, or maintenance of the system make a record of these tests, calibrations, or maintenance.
- 75.351(o)(3) requires that all records concerning the AMS be kept in a book or electronically in a computer system that is secure and not susceptible to alteration.
- 75.351(p) requires the mine operator to keep these records for at least one year at a surface location and to make them available for inspection by authorized representatives of the Secretary and representatives of miners.
- 75.351(q) requires that a record of the annual AMS operator training be kept. The record will include the content of training, the person conducting the training, and the date the training is conducted.
- 75.352(a) and 75.352(b) require the designated AMS operator or other appropriate personnel to take actions promptly when malfunction, alert, or alarm signals are received.

II. Desired Focus of Comments

MSHA is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

A copy of the proposed information collection request can be obtained by contacting the employee listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, or viewed on the Internet by selecting "Rules & Reg", and then selecting "FedReg.Docs". On the next screen, select "Paperwork Reduction Act Supporting Statement" to view documents supporting the **Federal Register** Notice.

III. Current Actions

This request for collection of information contains recordkeeping provisions for 30 CFR 75.350, 75.351, 75.352, 75.371 Safety Standards for Underground Coal Mine Ventilation—Belt Entry Used as an Intake Air Course To Ventilate Working Sections and Areas Where Mechanized Mining Equipment Is Being Installed or Removed. MSHA does not intend to publish the results of this information collection and is not seeking approval to not display the expiration date or OMB approval number for this collection of information.

There are no certification exceptions identified with this information collection and the collection of this information does not employ statistical methods.

Type of Review: Extension.

Agency: Mine Safety and Health Administration.

OMB Number: 1219–0138.

Frequency: On Occasion.
Affected Public: Business or other for-profit.
Cost to Federal Government: No cost to Federal Government.
Total Burden Respondents: 21.
Total Number of Responses: 251.
Total Burden Hours: 4,255.
Total Hour Burden Cost (operating/maintaining): $303,512.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: June 18, 2010.

Patricia W. Silvey,

Director, Office of Standards, and Regulations, and Variances.

[FR Doc. 2010–15270 Filed 6–23–10; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Proposed Information Collection Request Submitted for Public Comment and Recommendations; Operations Under Water (Pertains to Underground Coal Mines)

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments concerning the extension of the information collection related to the 30 CFR 75.1716, 75.1716–1 and 75.1716–3.

DATES: All comments must be received by midnight Eastern Daylight Savings Time on August 23, 2010.

ADDRESSES: Comments must clearly be identified with the rule title and may be submitted to MSHA by any of the following methods:

(1) *Electronic mail: zzMSHA-Comments@dol.gov.*

(2) *Facsimile:* (202) 693–9441.

(3) *Regular Mail:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2350, Arlington, VA 22209–3939.

(4) *Hand Delivery or Courier:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2350, Arlington, VA 22209–3939. Sign in at the receptionist's desk on the 21st floor.

FOR FURTHER INFORMATION CONTACT: Mario Distasio, Chief of the Economic Analysis Division, Office of Standards, Regulations, and Variances, MSHA, at *distasio.mario@dol.gov* (e-mail), 202–693–9445 (voicemail), 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Title 30 CFR 75.1716, 75.1716–1 and 75.1716–3 require operators of underground coal mines to provide MSHA notification before mining under bodies of water and to obtain a permit to mine under a body of water if, in the judgment of the Secretary, it is sufficiently large to constitute a hazard to miners. The regulation is necessary to prevent the inundation of underground coal mines with water which has the potential of drowning miners. Section 103(h) of the Mine Act, 30 U.S.C. 813, authorizes MSHA to collect information necessary to carryout its duty in protecting the safety and health of miners.

II. Desired Focus of Comments

MSHA is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

A copy of the proposed information collection request can be obtained by contacting the employee listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, or viewed on the Internet by selecting "Rules & Reg", and then selecting "FedReg.Docs". On the next screen, select "Paperwork Reduction Act Supporting Statement" to view documents supporting the **Federal Register** Notice.

III. Current Actions

This request for collection of information contains notification and recordkeeping provisions for the Proposed Information Collection Request Submitted for Public Comment and Recommendations; Operations Under Water (pertains to underground coal mines). MSHA does not intend to publish the results of this information collection and is not seeking approval to not display the expiration date or OMB approval number for this collection of information.

There are no certification exceptions identified with this information collection and the collection of this information does not employ statistical methods.

Type of Review: Extension.
Agency: Mine Safety and Health Administration.
OMB Number: 1219–0020.
Frequency: On Occasion.
Affected Public: Business or other for-profit.
Cost to Federal Government: $45,862.
Total Burden Respondents: 80.
Total Number of Responses: 80.
Total Burden Hours: 400.
Total Hour Burden Cost (operating/maintaining): $33,880.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: June 18, 2010.

Patricia W. Silvey,

Director, Office of Standards, and Regulations, and Variances.

[FR Doc. 2010–15271 Filed 6–23–10; 8:45 am]

BILLING CODE 4510–43–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: NARA is giving public notice that the agency proposes to request use of two forms to obtain authorization

from customers of the Office of Government Information Services (OGIS) to make inquiries on their behalf and to release information and records related to their Freedom of Information Act/Privacy Act requests/appeals. The public is invited to comment on the proposed information collection pursuant to the Paperwork Reduction Act of 1995.

DATES: Written comments must be received on or before August 23, 2010 to be assured of consideration.

ADDRESSES: Comments should be sent to: Paperwork Reduction Act Comments (NHP), Room 4400, National Archives and Records Administration, 8601 Adelphi Rd., College Park, MD 20740–6001; or faxed to 301–713–7409; or electronically mailed to *tamee.fechhelm@nara.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the proposed information collection and supporting statement should be directed to Tamee Fechhelm at telephone number 301–837–1694, or fax number 301–713–7409.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), NARA invites the general public and other Federal agencies to comment on proposed information collections. The comments and suggestions should address one or more of the following points: (a) Whether the proposed information collection is necessary for the proper performance of the functions of NARA; (b) the accuracy of NARA's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of information technology; and (e) whether small businesses are affected by this collection. The comments that are submitted will be summarized and included in the NARA request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this notice, NARA is soliciting comments concerning the following information collection:

Title: Freedom of Information Act (FOIA) Request for Assistance and Consent.

OMB number: 3095–00XX.

Agency form number: NA Forms 10003 and 10004.

Type of review: Regular.

Affected public: Individuals or households, Business or other for-profit, Not-for-profit institutions, and Federal Government.

Estimated number of respondents: 600.

Estimated time per response: 1 minute.

Frequency of response: On occasion.

Estimated total annual burden hours: 10 hours.

Abstract: In order to fulfill its government-wide statutory mission, OGIS provides varying types of assistance to its customers, which requires communicating with government departments and agencies regarding the customer's FOIA/Privacy Act request/appeal. Handling requests for OGIS assistance must conform to the legal requirements of the Freedom of Information Act (FOIA) and the Privacy Act of 1974. Authority for the requirements set forth in these forms is also contained in 5 U.S.C. 552a(b). OGIS will use the information submitted in the proposed forms to provide the requested assistance. Without the information submitted in these forms, OGIS would be unable to fulfill its mission.

Dated: June 21, 2010.

Martha Morphy,

Assistant Archivist for Information Services.

[FR Doc. 2010–15446 Filed 6–23–10; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request

AGENCY: National Science Foundation.

ACTION: Submission for OMB review; comment request.

SUMMARY: The National Science Foundation (NSF) has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. This is the second notice for public comment; the first was published in the **Federal Register** at 75 FR 18240, and no substantial comments were received. NSF is forwarding the proposed renewal submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice. The full submission may be found at: *http://www.reginfo.gov/public/do/PRAMain.* Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for National Science Foundation, 725—17th Street, NW., Room 10235, Washington, DC 20503, and to Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Boulevard, Suite 295, Arlington, Virginia 22230 or send e-mail to *splimpto@nsf.gov.* Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling 703–292–7556.

NSF may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number. Under OMB regulations, NSF may continue to conduct or sponsor the collection of information while this submission is pending at OMB.

SUPPLEMENTARY INFORMATION:

Title: Antarctic Conservation Act Application and Permit Form.

OMB Control Number: 3145–0034.

Proposed Project: The current Antarctic Conservation Act Application Permit Form (NSF 1078) has been in use for several years. The form requests general information, such as name, affiliation, location, *etc.,* and more specific information as to the type of object to be taken (plant, native mammal, or native bird).

Use of the Information: The purpose of the regulations (45 CFR part 670) is to conserve and protect the native mammals, birds, plants, and invertebrates of Antarctica and the ecosystem upon which they depend and to implement the Antarctic Conservation Act of 1978, Public Law 95–541, as amended by the Antarctic Science, Tourism, and Conservation Act of 1996, Public Law 104–227.

Burden on the Public: The Foundation estimates about 25 responses annually

at ½ hour per response; this computes to approximately 12.5 hours annually.

Dated: June 21, 2010.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2010–15347 Filed 6–23–10; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2010–0230]

Construction Reactor Oversight Process Request for Public Comment

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of opportunity for public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) staff is reconsidering the Construction Reactor Oversight Process (cROP), including the construction assessment process, as presented in IMC 2505, "Periodic Assessment of Construction Inspection Program Results," in order to propose policy options to the Commission to revise the oversight process. The staff proposal will include program oversight currently included as part of the Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) monitoring and closure processes, and evaluate the inclusion of objective performance monitoring elements such as construction program Performance Indicators (PIs) and a Significance Determination Process (SDP) analogous to those used in the Reactor Oversight Process (ROP) for the current operating reactor fleet.

DATES: The comment period expires August 9, 2010. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any one of the following methods. Please include Docket ID NRC–2010–0230 in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site *Regulations.gov.* Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2010–0230. Address questions about NRC dockets to Carol Gallagher 301–492–3668; e-mail *Carol.Gallagher@nrc.gov.*

Mail comments to: Cindy Bladey, Chief, Rules, Announcements and Directives Branch (RADB), Division of Administrative Services, Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by fax to RADB at (301) 492–3446.

You can access publicly available documents related to this notice using the following methods:

NRC's Public Document Room (PDR): The public may examine and have copied for a fee publicly available documents at the NRC's PDR, Public File Area O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

NRC's Agencywide Documents Access and Management System (ADAMS): Publicly available documents created or received at the NRC are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr.resource@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Kevin Mattern, Division of Construction Inspection and Operational Programs, U.S. Nuclear Regulatory Commission, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852–2738. Telephone: (301) 415–6622 or (301) 415–1395; Fax (301) 415–5400; E-mail: *Kevin.Mattern@nrc.gov.*

SUPPLEMENTARY INFORMATION: NRC staff are currently developing options and a recommendation to the Commission for a revised oversight process for new reactor construction with the objective of developing a risk-informed and performance based process, resulting in a more objective, predictable, and transparent process for licensees and members of the general public. To meet these objectives, the NRC staff is undertaking a comprehensive effort to develop a Construction Reactor Oversight Process using risk-informed and performance based tools. The NRC staff's efforts will be consistent with the recent Commission guidance in this area, notably the guidance provided in the Staff Requirements Memoranda (M081022) dated December 5, 2008 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML083400193).

In SECY–09–0113, "Update on the Development of Construction Assessment Process Policy Options and the Construction Inspection Program Information Management System," dated August 14, 2009 (Agencywide Documents Access and Management System Accession No. ML091970152), the NRC staff updated the Commission on the development of construction assessment process policy options.

Following the issuance of SECY–09–0113, the staff formed a cROP team in December 2009 with representatives from each regional office, the Office of Nuclear Reactor Regulation, the Office of Nuclear Security and Incident Response, and the Office of New Reactors. Team members offer a cross section of experience including personnel with extensive experience in developing and implementing the ROP. Through public workshops and stakeholder interactions, the cROP team is developing options for a cROP with elements similar to those used in the ROP. Specifically, the team is identifying the objectives, attributes, and activities that a construction oversight process would need to adequately and objectively assess licensee performance, as well as the sources of information necessary to support the assessment. These attributes include the application of thresholds to determine the significance of findings, a viable means to ensure appropriate NRC response to degrading licensee performance, and the assessment of licensee safety culture.

In SECY–10–0038, "Update Status on the Development of Construction Reactor Oversight Process Options," dated April 2, 2010 (Agencywide Documents Access and Management System Accession No. ML100550490), the NRC staff provided the Commission with an additional update on staff's progress toward the development of construction oversight process options for Commission consideration.

In order to ensure all stakeholder input is considered during development

of options for revising the cROP, NRC staff is seeking public comment and feedback on the specific topics highlighted in the questions below. In providing comments, each commenter's response should reference the number of the applicable question. Comments should be as specific as possible and should indicate why a commenter supports or does not support an aspect of this plan. The use of examples is encouraged.

(1) The staff has developed a draft of a new cROP regulatory framework, including cornerstone objectives, attributes and areas to measure (ADAMS Accession Nos. ML101050249; ML101050247). Are there important aspects of new reactor construction licensee performance that are not captured by the draft cROP regulatory framework?

(2) Is there a role for construction performance indicators as an input into the assessment of licensee construction activities? If so, what aspects of licensee activities during construction could be objectively measured by a PI? What should be considered in determining performance indicators and their thresholds?

(3) In the ROP, inspection findings are evaluated and given a color designation based on their safety significance using a risk-informed approach (the Significance Determination Process). What processes could be used to effectively and efficiently evaluate the safety significance of construction inspection findings?

(4) For the cROP, the staff intends to use a Construction Action Matrix similar to the ROP to assess licensee performance. Is there a more effective and efficient alternative approach that could be taken? If not, what inputs should be considered in the Construction Action Matrix?

(5) In the ROP, the NRC currently assigns safety culture component aspects to findings when appropriate. Substantive cross-cutting issues are identified when certain thresholds are crossed. Should the NRC treat findings in a similar manner in the construction environment?

(6) When is the appropriate time to transition from the cROP to the ROP? What is the basis for this proposed transition point?

(7) In addition to the previously mentioned issues, commenters are invited to give any other views on the NRC assessment process that could assist the NRC in improving its effectiveness.

End of Questions

Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the ADAMS Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/NRC/ADAMS/index.html.* If you do not have access to ADAMS or if you have problems accessing the documents in ADAMS, contact the NRC Public Document Room (PDR) reference staff at 1–800–397–4209 or 301–415–4737 or by e-mail to *pdr@nrc.gov.*

Dated at Rockville, Maryland this 16th day of June 2010.

For the Nuclear Regulatory Commission.

Mohammed Shuaibi,

Acting Deputy Director, Division of Construction Inspection & Operational Programs, Office of New Reactors.

[FR Doc. 2010–15321 Filed 6–23–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2010–0222]

Office of New Reactors; Proposed Revision to Standard Review Plan, Section 13.6.2, Revision 1 on Physical Security—Design Certification

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Solicitation of public comment.

SUMMARY: The NRC is soliciting public comment on NUREG–0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," on a proposed Revision 1 to Standard Review Plan (SRP), Section 13.6.2 on "Physical Security—Design Certification," (Agencywide Documents Access and Management System (ADAMS) Accession No. ML100640121). The Office of Nuclear Security and Incident Response is revising SRP Section 13.6.2, which updates the initial issuance of this section, dated March 2007, to reflect the changes of the recently issued Title 10 of the Code of Federal Regulations, part 73, Power Reactor Security Rule (published in the **Federal Register** (FR) on March 27, 2009 (74 FR 13926). The previous version of this SRP section was published in March 2007 as initial issuance (ADAMS Accession No. ML070720289).

The NRC staff issues notices to facilitate timely implementation of the current staff guidance and to facilitate activities associated with the review of amendment applications and review of design certification and combined license applications for the Office of New Reactors. The NRC staff intends to incorporate the final approved guidance into the next revision of NUREG–0800, SRP Section 13.6.2, Revision 1 and Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," June 2007.

DATES: Comments must be filed no later than 30 days from the date of publication of this notice in the **Federal Register**. Comments received after this date will be considered, if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any one of the following methods. Please include Docket ID NRC–2010–0222 in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC website and on the Federal rulemaking Web site at *http://www.regulations.gov.* Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2010–0222. Address questions about NRC dockets to Carol Gallagher 301–492–3668; e-mail at *Carol.Gallagher@nrc.gov.*

Mail comments to: Cindy Bladey, Chief, Rulemaking, Announcements and Directives Branch (RADB), Division of Administrative Services, Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by fax to RDB at 301–492–3446.

You can access publicly available documents related to this notice using the following methods:

NRC's Public Document Room (PDR): The public may examine and have copied for a fee publicly available documents at the NRC's PDR, Public File Area O1 F21, One White Flint

North, 11555 Rockville Pike, Rockville, Maryland.

The NRC ADAMS provides text and image files of NRC's public documents. These documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS, or who encounter problems in accessing the documents located in ADAMS, should contact the NRC Public Document Room reference staff at 1–800–397–4209, 301–415–4737, or by e-mail at *pdr.resources@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. William F. Burton, Chief, Rulemaking and Guidance Development Branch, Division of New Reactor Licensing, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone at 301–415–6332 or e-mail at *william.burton@nrc.gov.*

The NRC staff is issuing this notice to solicit public comments on the proposed SRP Section 13.6.2, Revision 1. After the NRC staff considers any public comments, it will make a determination regarding the proposed SRP Section 13.6.2, Revision 1.

Dated at Rockville, Maryland, this 15th day of June 2010.

For the Nuclear Regulatory Commission.

William F. Burton,

Chief, Rulemaking and Guidance Development Branch, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2010–15316 Filed 6–23–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2010–0223]

Office of New Reactors; Proposed Revision to Standard Review Plan Section 13.6.3, Revision 1 on Physical Security—Early Site Permit

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Solicitation of public comment.

SUMMARY: The NRC is soliciting public comment on NUREG–0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," on a proposed Revision 1 to Standard Review Plan (SRP), Section 13.6.3 on "Physical Security—Early Site Permit," (Agencywide Documents Access and Management System (ADAMS) Accession No. ML100980132). The Office of Nuclear Security and Incident Response is revising SRP Section 13.6.3, which updates the initial issuance of this section, dated March 2007, to reflect the changes of the recently issued Title 10 of the Code of Federal Regulations, part 73, Power Reactor Security Rule (published in the **Federal Register** (FR) on March 27, 2009 (74 FR 13926). The previous version of this SRP section was published in March 2007 as initial issuance (ADAMS Accession No. ML070720310).

The NRC staff issues notices to facilitate timely implementation of the current staff guidance and to facilitate activities associated with the review of amendment applications and review of design certification and combined license applications for the Office of New Reactors. The NRC staff intends to incorporate the final approved guidance into the next revision of NUREG–0800, SRP Section 13.6.3, Revision 1 and Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," June 2007.

DATES: Comments must be filed no later than 30 days from the date of publication of this notice in the **Federal Register**. Comments received after this date will be considered, if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any one of the following methods. Please include Docket ID NRC–2010–0223 in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site at *http://www.regulations.gov.* Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2010–0223. Address questions about NRC dockets to Carol Gallagher at 301–492–3668; e-mail at *Carol.Gallagher@nrc.gov.*

Mail comments to: Cindy Bladey, Chief, Rulemaking, Announcements and Directives Branch (RADB), Division of Administrative Services, Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by fax to RADB at 301–492–3446.

You can access publicly available documents related to this notice using the following methods:

NRC's Public Document Room (PDR): The public may examine and have copied for a fee publicly available documents at the NRC's PDR, Room O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

The NRC ADAMS provides text and image files of NRC's public documents. These documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS, or who encounter problems in accessing the documents located in ADAMS, should contact the NRC Public Document Room reference staff at 1–800–397–4209, 301–415–4737, or by e-mail at *pdr.resources@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. William F. Burton, Chief, Rulemaking and Guidance Development Branch, Division of New Reactor Licensing, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone at 301–415–6332 or e-mail at *william.burton@nrc.gov.*

The NRC staff is issuing this notice to solicit public comments on the proposed SRP Section 13.6.3, Revision 1. After the NRC staff considers any public comments, it will make a determination regarding the proposed SRP Section 13.6.3, Revision 1.

Dated at Rockville, Maryland, this 15th day of June 2010.

For the Nuclear Regulatory Commission.

William F. Burton,

Chief, Rulemaking and Guidance Development Branch, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2010–15319 Filed 6–23–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2010–0228]

Office of New Reactors; Proposed Revision to Standard Review Plan Section 13.6.1, Revision 1 on Physical Security—Combined License and Operating Reactors

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Solicitation of public comment.

SUMMARY: The NRC is soliciting public comment on NUREG–0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," on a proposed Revision 1 to Standard Review Plan (SRP), Section 13.6.1 on "Physical Security—Combined License and Operating Reactors," (Agencywide Documents Access and Management System (ADAMS) Accession No. ML100350158). The Office of Nuclear Security and Incident Response is revising SRP Section 13.6.1, which updates the initial issuance of this section, dated March 2007, to reflect the changes of the recently issued Title 10 of the Code of Federal Regulations, part 73, Power Reactor Security Rule (published in the **Federal Register** (FR) on March 27, 2009 (74 FR 13926). The previous version of this SRP section was published in March 2007 as initial issuance (ADAMS Accession No. ML070720094).

The NRC staff issues notices to facilitate timely implementation of the current staff guidance and to facilitate activities associated with the review of amendment applications and review of design certification and combined license applications for the Office of New Reactors. The NRC staff intends to incorporate the final approved guidance into the next revision of NUREG–0800, SRP Section 13.6.1, Revision 1 and Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," June 2007.

DATES: Comments must be filed no later than 30 days from the date of publication of this notice in the FR. Comments received after this date will be considered, if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any one of the following methods. Please include Docket ID NRC–2010–0228 in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site at *http://www.regulations.gov.* Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2010–0228. Address questions about NRC dockets to Carol Gallagher at 301–492–3668; e-mail at *Carol.Gallagher@nrc.gov.*

Mail comments to: Cindy Bladey, Chief, Rulemaking, Announcements and Directives Branch (RADB), Division of Administrative Services, Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by fax to RADB at 301–492–3446.

You can access publicly available documents related to this notice using the following methods:

NRC's Public Document Room (PDR): The public may examine and have copied for a fee publicly available documents at the NRC's PDR, Room O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

The NRC ADAMS provides text and image files of NRC's public documents. These documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS, or who encounter problems in accessing the documents located in ADAMS, should contact the NRC Public Document Room reference staff at 1–800–397–4209, 301–415–4737, or by e-mail at *pdr.resources@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. William F. Burton, Chief, Rulemaking and Guidance Development Branch, Division of New Reactor Licensing, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone at 301–415–6332 or e-mail at *william.burton@nrc.gov.*

The NRC staff is issuing this notice to solicit public comments on the proposed SRP Section 13.6.1, Revision 1. After the NRC staff considers any public comments, it will make a determination regarding the proposed SRP Section 13.6.1, Revision 1.

Dated at Rockville, Maryland, this 15th day of June 2010.

For the Nuclear Regulatory Commission,

William F. Burton,

Chief, Rulemaking and Guidance Development Branch, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2010–15323 Filed 6–23–10; 8:45 am]

BILLING CODE 7590–01–P

PENSION BENEFIT GUARANTY CORPORATION

Proposed Submission of Information Collection for OMB Review; Comment Request; Annual Reporting and Disclosure

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of intention to request extension of OMB approval of revised collection of information.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) intends to request that the Office of Management and Budget (OMB) extend approval, under the Paperwork Reduction Act, of its collection of information for annual reporting and disclosure under 29 CFR Part 2520 (OMB control number 1212–0057, expires September 30, 2010), without change. This notice informs the public of PBGC's intent and solicits public comment on the collection of information.

DATES: Comments must be submitted by August 23, 2010.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the Web site instructions for submitting comments.
- *E-mail: reg.comments@pbgc.gov.*
- *Fax:* 202–326–4224.
- *Mail or Hand Delivery:* Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026.

Comments received, including personal information provided, will be posted to *http://www.pbgc.gov.*

Copies of the collection of information and comments may be obtained without charge by writing to the Disclosure Division, Office of General Counsel, at the above address or by visiting the Disclosure Division or calling 202–326–4040 during normal business hours. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4040.)

FOR FURTHER INFORMATION CONTACT: Grace Kraemer, Attorney, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026; 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: The Employee Retirement Income Security

Act of 1974 (ERISA) contains three separate sets of provisions—in Title I (Labor provisions), Title II (Internal Revenue Code provisions), and Title IV (PBGC provisions)—requiring administrators of employee benefit pension and welfare plans (collectively referred to as employee benefit plans) to file returns or reports annually with the federal government.

Since enactment of ERISA, PBGC, the Department of Labor (DOL), and the Internal Revenue Service (IRS) (collectively, the Agencies), have worked together (under DOL's leadership) to produce the Form 5500 Annual Return/Report, through which the regulated public can satisfy the combined reporting/filing requirements applicable to employee benefit plans.

The Form 5500 Series is the primary source of information concerning the operation, funding, assets and investments of pension and other employee benefit plans. In addition to being an important disclosure document for plan participants and beneficiaries, the Form 5500 is a compliance and research tool for the Agencies, and a source of information for use by other federal agencies, Congress, and the private sector in assessing employee benefit, tax, and economic trends and policies.

On November 16, 2007, the Agencies adopted revisions to the Form 5500 Annual Return/Report in order to update and streamline the annual reporting process in conjunction with establishing a wholly electronic processing system for the receipt of the Form 5500 Annual Return/Reports and to conform the forms and instructions to the provisions of the Pension Protection Act of 2006 (PPA).

OMB has approved PBGC's annual reporting and disclosure collection of information (2008–2010 Forms and Instructions) under control number 1212–0057 (expires September 30, 2010). PBGC intends to request that OMB extend approval of this collection of information for three years, without change. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

PBGC estimates that it will receive 30,300 Form 5500 and Form 5500–SF filings per year under this collection of information. PBGC further estimates that the total annual burden of this collection of information is 1,200 hours and $1,250,000.

PBGC is soliciting public comments to—

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodologies and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Issued in Washington, DC, this 21st day of June 2010.

John H. Hanley,

Director, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation.

[FR Doc. 2010–15339 Filed 6–23–10; 8:45 am]

BILLING CODE 7709–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

Green Energy Resources, Inc.; Order of Suspension of Trading

June 22, 2010.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Green Energy Resources, Inc. ("Green Energy") because of questions regarding the accuracy of statements by Green Energy in press releases concerning, among other things, the company's involvement in the Gulf of Mexico oil spill cleanup effort.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of Green Energy.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed company is suspended for the period from 9:30 a.m. EDT June 22, 2010 through 11:59 p.m. EDT, on July 6, 2010.

By the Commission.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2010–15425 Filed 6–22–10; 4:15 pm]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–62314; File No. SR–NASDAQ–2010–072]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change by The NASDAQ Stock Market LLC To Clarify the Applicable Time Period of Trading Pauses on Trading Days With an Early Scheduled Close

June 17, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 14, 2010, The NASDAQ Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as constituting a non-controversial rule change under Rule 19b-4(f)(6) under the Act,[3] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to clarify the applicable time period of trading pauses on trading days with an early scheduled close.

The text of the proposed rule change is below. Proposed new language is underlined and proposed deletions are in brackets.[4]

* * * * *

4120. Trading Halts

(a) Authority To Initiate Trading Halts or Pauses

In circumstances in which Nasdaq deems it necessary to protect investors and the public interest, Nasdaq, pursuant to the procedures set forth in paragraph (c):

(1)–(10) No Change.

(11) shall, between 9:45 a.m. and 3:35 p.m., *or in the case of an early scheduled close, 25 minutes before the close of trading,* immediately pause

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] Changes are marked to the rule text that appears in the electronic manual of NASDAQ found at *http://nasdaqomx.cchwallstreet.com.*

trading for 5 minutes in any Nasdaq-listed security when the price of such security moves 10 percent or more within a 5-minute period. At the end of the trading pause, Nasdaq will re-open the security using the Halt Cross process set forth in Nasdaq Rule 4753. In the event of a significant imbalance at the end of a trading pause, Nasdaq may delay the re-opening of a security.

Nasdaq will issue a notification if it cannot resume trading for a reason other than a significant imbalance.

Price moves under this paragraph will be calculated by changes in each consolidated last-sale price disseminated by a network processor over a five minute rolling period measured continuously. Only regular way in-sequence transactions qualify for use in calculations of price moves. Nasdaq can exclude a transaction price from use if it concludes that the transaction price resulted from an erroneous trade.

If a trading pause is triggered under this paragraph, Nasdaq shall immediately notify the single plan processor responsible for consolidation of information for the security pursuant to Rule 603 of Regulation NMS under the Securities Exchange Act of 1934.

If a primary listing market issues an individual stock trading pause, Nasdaq will pause trading in that security until trading has resumed on the primary listing market or notice has been received from the primary listing market that trading may resume. If the primary listing market does not reopen within 10 minutes of notification of a trading pause, Nasdaq may resume trading the security.

The provisions of this paragraph shall only apply to securities in the Standard & Poor's 500 Index.

The provisions of this paragraph shall be in effect during a pilot set to end on December 10, 2010.

(b)–(c) No Change.

* * * * *

(b) Not applicable.

(c) Not applicable.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq proposes to clarify the applicable time period of trading pauses on trading days with an early scheduled close. Under the proposal, trading pauses on days with an early scheduled close would be initiated no later than 25 minutes before that close. On trading days with an early scheduled close, the proposal will ensure a minimum pause-free time period before the close exactly the same as that applicable on trading days with a regular 4 p.m. close.

2. Statutory Basis

NASDAQ believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[5] in general, and with Sections 6(b)(5) of the Act,[6] in particular, in that the proposal is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange believes that the proposed rule meets these requirements in that it promotes uniformity regarding pause periods on all trading days.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[7] and Rule 19b–4(f)(6) thereunder.[8] The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative upon filing. The Commission notes that the proposed rule change clarifies how the Exchange handles Trading Pauses in the case of an early scheduled closing of the Exchange which is the same way the other listing markets will handle Trading Pauses during an early scheduled closing, and how indications will be published during all Trading Pauses. The proposed rule change does not raise any new substantive issues. For these reasons, the Commission believes that the waiver of the 30-day operative delay is consistent with the protection of investors and the public interest.[9]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2010–072 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(6).

[9] For purposes only of waiving the 30-day operative delay of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

All submissions should refer to File Number SR–NASDAQ–2010–072. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method.

The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of NASDAQ. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–NASDAQ–2010–072 and should be submitted on or before July 15, 2010.

For the Commission, by the Division of Trading & Markets, pursuant to delegated authority.[10]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–15247 Filed 6–23–10; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–62321; File No. SR–NYSEArca–2010–46]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Commentary .01 to Rule 5.32 To Permit Certain FLEX Options To Trade Under the FLEX Trading Procedures for a Limited Time on a Closing Only Basis

June 17, 2010.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on June 2, 2010, NYSE Arca, Inc. ("NYSE Arca" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend Commentary .01 to Rule 5.32, Terms of FLEX Options, to permit certain FLEX Options to trade under the FLEX Trading Procedures for a limited time. The text of the proposed rule change is attached at Exhibit 5 to the 19b–4 form. A copy of this filing is available on the Exchange's Web site at *http://www.nyse.com,* on the Commission's Web site at *http://www.sec.gov,* at the Exchange's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to allow certain FLEX options, which are identical in all terms to a Non-FLEX option, to trade using FLEX Trading Procedures for the balance of the trading day on which the Non-FLEX Option is added as an intra-day add.

The Exchange recently adopted rule changes to allow FLEX options to expire within two business days of a third-Friday-of-the-month expiration, including expiration Friday ("expiration FLEX").[4] Such FLEX Options could have either an American Style exercise or a European Style exercise. The same rule change also allowed for FLEX Index Options to expire on or within two business days of a third-Friday-of-the-month expiration, provided they only have an exercise settlement value on the expiration date determined by reference to the reported level of the index as derived from the opening prices of the component securities ("a.m. settlement").

The rule change provided that expiration FLEX options will be permitted before (but not after) Non-FLEX Options with identical terms are listed. Once and if an option series is listed for trading as a Non-FLEX Option series, (i) all existing open positions established under the FLEX Trading procedures shall be fully fungible with transactions in the respective Non-FLEX Options series, and (ii) any further trading in the series would be as Non-FLEX Options subject to the Non-FLEX trading procedures and rules.

The Options Clearing Corporation ("OCC") became concerned that, in certain circumstances, in the event a Non-FLEX Option is listed with identical terms to an existing FLEX option, OCC could not net the positions in the contracts until the next business day. If the Non-FLEX Option were listed intra-day, and the holder of a position in the FLEX option attempted to close the position using the Non-FLEX Option, the holder would be technically long in one contract and short in the other contract. This would expose the holder to assignment risk until the next day despite having offsetting positions.

The limited circumstances are:

- The Non-Flex Option is listed intra-day.
- The FLEX contract is for American style exercise.
- All other terms are identical and the contracts are otherwise fungible.

The risk does not occur in expiration Friday FLEX option positions during the five days prior to expiration, as no new Non-FLEX Option series may be listed within five days of expiration. It also does not exist for FLEX option positions that will be identical to Non-FLEX series to be added after expiration, as those new series are added "overnight" and OCC will convert the FLEX position to the Non-FLEX Options series at the time the Non-FLEX series is created. Further, it does not exist for FLEX Index Options listed on NYSE Arca, as Non-FLEX Index options currently traded on

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Exchange Act Release No. 60549, SR–NYSE–Arca–2009–75 (August 20, 2009), 74 FR 44415 (August 28, 2009).

NYSE Arca are all European style exercise, and thus the Non-FLEX Index Options cannot be exercised on the day the series is listed.

As an example, suppose underlying issue XYZ, trading around $25 per share, has options listed on the March cycle, and in February an investor wishes to buy just-out-of-the-money call options that will expire in May. Since the Non-FLEX May Options will not be listed until after the March expiration, the investor enters a FLEX Option order in February to buy 250 Call 30 options expiring on the third Friday of May. If, as expected, the Non-FLEX May 30 call options are listed on the Monday after March expiration, the investor's open FLEX position will be converted by OCC over the weekend following March expiration to the Non-FLEX series.

However, if XYZ stock should decline between the time of the FLEX transaction and March expiration, the May 30 calls may not be added after March expiration. If that were to occur, the May 30 calls may be added sometime later. Suppose the Exchange receives a request to add the May 30 calls on the morning of the Wednesday after expiration, and the Exchange lists them immediately. The investor with the FLEX position may then decide it is an opportune time to close his position.

Under current rules, the investor would be required to close the position by entering a sell order in the new Non-FLEX Option series. However, when the Non-FLEX transaction is reported to OCC, the investor is considered short in the Non-FLEX Option series, and is still long in the FLEX Option. OCC cannot aggregate the FLEX positions into the Non-FLEX series until after exercise and assignment processing. If a buyer in the new Non-FLEX series were to exercise the options, the original investor who had attempted to close the FLEX position with an offsetting Non-FLEX trade would be at risk of being assigned on the technically short Non-FLEX position.

Because of this risk, OCC will not clear an American style expiration Friday FLEX option. The Exchange has spoken to OCC, and OCC has agreed that allowing the holder of an open position in a FLEX contract to close the position using a FLEX option in such circumstances will mitigate the risk.

The assignment risk does not exist if the Non-FLEX option is to be added the next trading day. In situations where OCC is aware that a series will be added overnight, they can convert the FLEX Position to a Non-FLEX position before the next trading day. However, OCC cannot guarantee that an identical Non-FLEX series will not be added intra-day, and thus will not clear such American style FLEX options.

NYSE Arca is proposing a limited exception to the requirement that the trading in such options be under the Non-FLEX Trading Procedures. The Exchange proposes that, in the event a Non-FLEX Option is listed intra-day, the holder of a FLEX Option with identical terms could close the FLEX position under the FLEX Trading procedures, but only for the balance of the trading day on which the series is added. Under the proposed rule change, both sides of the FLEX transaction would have to be closing only positions.

This change will allow the holder of a FLEX position to trade in such a manner to mitigate the assignment risk.

A FLEX Post Official [5] has the regulatory responsibility for reviewing the conformity of FLEX trades to the terms and specifications contained in Rule 5.32. In the event a Non-FLEX series, having the same terms as an existing expiration Friday FLEX option, is listed intra-day, the FLEX Post Official will review any subsequent FLEX transactions in that series and verify that the order is being executed for the purpose of closing out an existing FLEX position. The FLEX Post Official will not disseminate a FLEX Request for Quote for any order representing a FLEX series having the same terms as a Non-FLEX series, unless such FLEX order is a closing order (and it is the day the Non-FLEX series has been added). In addition, if the FLEX Post Official were to disseminate a FLEX Request for Quotes for a closing order representing a FLEX series having the same terms as a Non-FLEX series, the FLEX Post Official would only accept response quotes and orders from Options Trading Permit ("OTP") Holders that were closing out an existing FLEX position.

The NYSE Regulatory Department reviews FLEX trading activity, and, in the event a non-FLEX series with the same terms as an expiration Friday FLEX option is listed intra-day, will review any subsequent FLEX transactions in the series to verify that they are closing a position.[6]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) [7] of the Securities Exchange Act of 1934 (the "Act"), in general, and furthers the objectives of Section 6(b)(5) [8] in particular in that it is designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, to remove impediments to and to perfect the mechanism for a free and open market and a national market system and, in general, to protect investors and the public interest, by giving OTP Holders, OTP Firms, and investors with additional tools to trade customized options in an exchange environment while allowing the holder of a FLEX position to trade in such a manner as to mitigate inadvertent assignment risk.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [9] and Rule 19b–4(f)(6) thereunder.[10] Because the proposed rule change does not:
(i) Significantly affect the protection of investors or the public interest;
(ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and Rule 19b–4(f)(6)(iii) thereunder.[12]

[5] FLEX Post Officials are Exchange employees designated pursuant to Rule 5.38(a).

[6] Through a Regulatory Services Agreement ("RSA") between NYSE Regulation, Inc. ("NYSE Regulation") and NYSE Arca, staff of NYSE Regulation conducts, among other things, surveillances of the NYSE Arca options trading platform for purposes of monitoring compliance with the relevant trading rules by NYSE Arca participants. NYSE Arca represents that, through this RSA, there are appropriate surveillance in place to monitor transactions in FLEX options.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires that a self-regulatory organization submit to the Commission written notice of its intent to file the proposed rule change,

Continued

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2010–46 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2010–46. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NYSEArca–2010–46 and should be submitted on or before July 15, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–15248 Filed 6–23–10; 8:45 am]

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along with a brief description and text of the proposed rule change, at least five business days prior to the filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission notes that the Exchange has satisfied this requirement.

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–62320; File No. SR–Phlx–2010–83]

Self-Regulatory Organizations; NASDAQ OMX PHLX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify Its Rules Relating to Directed Orders and Eligible Orders

June 17, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 14, 2010, NASDAQ OMX PHLX, Inc. ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to clarify the definition of "Directed Order" in Rule 1080(l)(i)(A) by removing the limiting word "customer" before the word "order." A conforming change to the definition of "Order Flow Provider" is proposed to be made in Rule 1080(l)(i)(B). Second, amendments to Rule 1080(b)(i)(C) are proposed which specify that orders for the account of an off-floor broker dealer may be entered into the Exchange's enhanced electronic trading platform for options, Phlx XL,[5] by an agent of the off-floor broker dealer. Third, the Exchange is adding opening-only-market orders and limit on opening orders to the list of eligible orders in Rule 1080(b)(i), as order types eligible for entry into the trading system. The Exchange proposes to add a definition of limit on opening order to Rule 1066.

The text of the proposed rule change is available on the Exchange's Internet Web site at *http://www.nasdaqtrader.com/micro.aspx?id=PHLXRulefilings,* on the Commission's Internet Web site at *http://www.sec.gov,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In May 2005 the Exchange adopted rules for Phlx XL that permit Exchange specialists, Streaming Quote Traders ("SQTs"),[6] and Remote Streaming Quote Traders ("RSQTs")[7] to receive Directed Orders, and to provide a participation guarantee to specialists, SQTs and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Securities Exchange Act Release No. 59995 (May 28, 2009), 74 FR 26750 (June 3, 2009) (SR–Phlx–2009–32).

[6] An SQT is an Exchange Registered Options Trader ("ROT") who has received permission from the Exchange to generate and submit option quotations electronically through Phlx XL in eligible options to which such SQT is assigned. An SQT may only submit such quotations while such SQT is physically present on the floor of the Exchange. *See* Phlx Rule 1014(b)(ii)(A).

[7] An RSQT is an ROT that is a member or member organization with no physical trading floor presence who has received permission from the Exchange to generate and submit option quotations electronically through Phlx XL in eligible options to which such RSQT has been assigned. An RSQT may only submit such quotations electronically from off the floor of the Exchange. *See* Phlx Rule 1014(b)(ii)(B).

RSQTs that receive Directed Orders.[8] The proposed amendment to Rule 1080(l)(i)(A) is intended to clarify that Rule 1080(1)(i)(A) does not limit Directed Orders to public customer orders. The Exchange notes that other exchanges' Directed Orders rules do not limit Directed Orders to public customer orders.[9]

Currently, the term "Directed Order" is defined in Rule 1080(l)(i)(A) as "any customer order (other than a stop or stop-limit order as defined in Rule 1066) to buy or sell which has been directed to a particular specialist, RSQT, or SQT by an Order Flow Provider * * *" The Exchange proposes to remove the word "customer" from this definition to avoid any suggestion that Directed Orders are limited to orders of "public" customers. Directed Orders can be broker-dealer orders as well as public customer orders.

Rule 1080(b)(i)(A) provides in relevant part that "[f]or purposes of Exchange options trading, an agency order is any order entered on behalf of a public customer, and does not include any order entered for the account of a broker-dealer, or any account in which a broker-dealer or an associated person of a broker-dealer has any direct or indirect interest." In adopting the Directed Order program, the Exchange did not limit Directed Orders to agency orders as defined in Rule 1080(b)(i)(A). The Exchange believes, however, that use of the word "customer" in the definition of Directed Order is potentially confusing and unnecessary and is therefore deleting it. For the same reason, the modifier "customer" is deleted before the word "order" in the definition of Order Flow Provider in Rule 1080(l)(i)(B). Accordingly, this change clarifies that Directed Orders can be sent not only on behalf of public customers but also on behalf of broker dealers. Directed Orders are limited to orders sent on an agency basis by Order Flow Providers and not on behalf of the sender's proprietary account.

Currently, Rule 1080(b)(i)(C) provides that certain "off-floor broker-dealer" limit orders may be entered into Phlx XL. The rule currently defines "off-floor broker-dealer" as a broker-dealer that delivers orders from off the floor of the Exchange for the proprietary account(s) of such broker-dealer. Rule 1080(b)(i)(C) is being revised to specify that orders for an off-floor broker-dealer's proprietary account may be entered into Phlx XL by an agent, on behalf of the off-floor broker-dealer as well as by the off-floor broker-dealer itself. This situation occurs, for example, where the off-floor broker-dealer is not itself a Phlx member and uses a Phlx member for execution of its proprietary orders on Phlx.

Rule 1080(b)(i) lists the types of orders that are eligible for entry into the Phlx XL trading system by various categories of market participants. The Exchange is proposing to add opening-only-market orders to the list of agency orders eligible for entry into the system in Rule 1080(b)(i)(A).[10] It also proposes to add limit-on-opening orders to each of the lists of eligible orders that market participants are permitted to enter in Rules 1080(b)(i)(A), (B) and(C). "Limit-on-Opening Order" would be defined in new Section 9 of Rule 1066(c) as meaning a limit order which is to be executed in whole or in part during the opening rotation of an options series or not at all. Phlx notes that at least one other options exchange already accepts opening only limit and market orders.[11]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [12] in general, and furthers the objectives of Section 6(b)(5) of the Act [13] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by permitting the Exchange to modify its rules relating to Directed Orders and eligible orders for the benefit of investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing rule does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [14] and Rule 19b–4(f)(6) thereunder.[15]

At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–Phlx–2010–83 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx-2010–83. This file number should be included on the

[8] *See* Securities Exchange Act Release No. 51759 (May 27, 2005), 70 FR 32860 (June 6, 2005). *See also* Phlx Rule 1014(g)(viii) (setting forth the automatic trade allocation algorithm for Directed Orders).

[9] *See, e.g.,* NYSE Amex Rule 900.3NY(s), NYSE Arca Rule 6.62(z) and ISE Rule 811(a)(1).

[10] Rule 1066(c)(5) provides that "[a]n opening-only-market order is a market order which is to be executed in whole or in part during the opening rotation of an options series or not at all."

[11] See NYSE Arca Rule 6.62(r) which defines an "Opening Only Order" as "a market order or limit order which is to be executed in whole or in part during the opening auction of an options series or not at all. Any portion not so executed is to be treated as cancelled."

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6). Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2010–83 and should be submitted on or before July 15, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Florence E. Harmon,

Deputy Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–62319; File No. SR–ISE–2010–57]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Fees and Rebates for Adding and Removing Liquidity

June 17, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 1, 2010, the International Securities Exchange, LLC (the "ISE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The ISE is proposing to amend its Schedule of Fees in order to increase the number of options classes to be included in the Exchange's current schedule of transaction fees and rebates for adding and removing liquidity. The text of the proposed rule change is available on the Exchange's Web site (*http://www.ise.com*), at the principal office of the Exchange, at the Commission's Public Reference Room, and on the Commission's Web site at *http://www.sec.gov.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to increase liquidity and attract order flow by amending its transaction fees and rebates for adding and removing liquidity ("maker/taker fees").[3] The Exchange's maker/taker fees currently apply to the following categories of market participants: (i) Market Maker; (ii) Market Maker Plus;[4] (iii) Non-ISE Market Maker;[5] (iv) Firm Proprietary; (v) Customer (Professional);[6] (vi) Priority Customer,[7] 100 or more contracts; and (vii) Priority Customer, less than 100 contracts.[8]

Current Transaction Charges for Adding and Removing Liquidity

The Exchange currently assesses a per contract transaction charge to market participants that remove, or "take," liquidity from the Exchange in the following 20 options classes: PowerShares QQQ trust ("QQQQ"), Bank of America Corporation ("BAC"), Citigroup, Inc. ("C"), Standard and Poor's Depositary Receipts/SPDRs ("SPY"), iShares Russell 2000 ("IWM"), Financial Select Sector SPDR ("XLF"), Apple, Inc. ("AAPL"), General Electric Company ("GE"), JPMorgan Chase & Co. ("JPM"), Intel Corporation ("INTC"), Goldman Sachs Group, Inc. ("GS"), Research in Motion Limited ("RIMM"), AT&T, Inc. ("T"), Verizon

[16] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] These fees are similar to the "maker/taker" fees currently assessed by NASDAQ OMX PHLX ("PHLX"). PHLX currently charges a fee for removing liquidity to the following class of market participants: (i) Customer, (ii) Directed Participant, (iii) Specialist, ROT, SQT and RSQT, (iv) Firm, (v) Broker-Dealer, and (vi) Professional. PHLX also provides a rebate for adding liquidity to the following class of market participants: (i) Customer, (ii) Directed Participant, (iii) Specialist, ROT, SQT and RSQT, and (iv) Professional. *See* Securities Exchange Act Release Nos. 61684 (March 10, 2010), 75 FR 13189 (March 18, 2010); 61932 (April 16, 2010), 75 FR 21375 (April 23, 2010); and 61961 (April 22, 2010), 75 FR 22881 (April 30, 2010).

[4] A Market Maker Plus is a market maker who is on the National Best Bid or National Best Offer 80% of the time in that symbol during the current trading month for series trading between $0.03 and $5.00 in premium. The Exchange determines whether a market maker qualifies as a Market Maker Plus at the end of each month by looking back at each market maker's quoting statistics during that month. If at the end of the month, a market maker meets the 80% criteria, the Exchange rebates $0.10 per contract for transactions executed by that market maker during that month. The Exchange provides market makers a report on a daily basis with quoting statistics so that market makers can determine whether or not they are meeting the 80% criteria. On May 26, 2010, the Exchange submitted a proposed rule change, SR–ISE–2010–54, to be effective on June 1, 2010, to amend the qualification standards for market makers to receive the $0.10 per contract rebate. Pursuant to that proposed rule change, a market maker must be on the National Best Bid or National Best Offer 80% of the time for series trading between $0.03 and $5.00 in premium in each of the front two expiration months and 80% of the time for all series trading between $0.03 and $5.00 in order to receive the rebate.

[5] A Non-ISE Market Maker, or Far Away Market Maker ("FARMM"), is a market maker as defined in Section 3(a)(38) of the Securities Exchange Act of 1934, as amended ("Exchange Act"), registered in the same options class on another options exchange.

[6] A Customer (Professional) is a person who is not a broker/dealer and is not a Priority Customer.

[7] A Priority Customer is defined in ISE Rule 100(a)(37A) as a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s).

[8] The Chicago Board Options Exchange ("CBOE") currently makes a similar distinction between large size customer orders that are fee liable and small size customer orders whose fees are waived. CBOE currently waives fees for customer orders of 99 contracts or less in options on exchange-traded funds ("ETFs") and Holding Company Depositary Receipts ("HOLDRs") and charges a transaction fee for customer orders that exceed 99 contracts. *See* Securities Exchange Act Release No. 59892 (May 8, 2009), 74 FR 22790 (May 14, 2009).

Communications, Inc. ("VZ"), United States Natural Gas Fund ("UNG"), Freeport-McMoRan Copper & Gold, Inc. ("FCX"), Cisco Systems, Inc. ("CSCO"), Diamonds Trust, Series 1 ("DIA"), Amazon.com, Inc. ("AMZN") and United States Steel Corporation ("X"). The per contract transaction charge depends on the category of market participant submitting an order or quote to the Exchange that removes liquidity.[9] Priority Customer Complex orders, regardless of size, are not assessed a fee for removing liquidity.

The Exchange also currently assesses transaction charges for adding liquidity in options on QQQQ, BAC, C, SPY, IWM, XLF, AAPL, GE, JPM, INTC, GS, RIMM, T, VZ, UNG, FCX, CSCO, DIA, AMZN and X. Priority Customer orders, regardless of size, and Market Maker Plus orders are not assessed a fee for adding liquidity.

Current Rebates

In order to promote and encourage liquidity in options classes that are subject to maker/taker fees, the Exchange currently offers a $0.10 per contract rebate for Market Maker Plus orders sent to the Exchange.[10] Further, in order to incentivize members to direct retail orders to the Exchange, Priority Customer Complex orders, regardless of size, currently receive a rebate of $0.15 per contract on all legs when these orders trade with non-customer orders in the Exchange's Complex Orderbook. Additionally, the Exchange's Facilitation Mechanism has an auction which allows for participation in a trade by members other than the member who entered the trade. To incentivize members, the Exchange currently offers a rebate of $0.15 per contract to contracts that do not trade with the contra order in the Facilitation Mechanism.

Fee Changes

The Exchange proposes to add the following 30 options classes to be included in the Exchange's maker/taker fee schedule: Alcoa Inc. ("AA"), American International Group, Inc. ("AIG"), American Express Company ("AXP"), Best Buy Company ("BBY"), Caterpillar, Inc. ("CAT"), Chesapeake Energy Corporation ("CHK"), Dendreon Corporation ("DNDN"), iShares MSCI Emerging Markets Index Fund ("EEM"), iShares MSCI EAFE Index Fund ("EFA"), iShares MSCI Brazil Index Fund ("EWZ"), Ford Motor Company ("F"), Direxion Shares Financial Bull ("FAS"), Direxion Shares Financial Bear ("FAZ"), First Solar, Inc. ("FSLR"), Market Vectors ETF Gold Miners ("GDX"), SPDR Gold Trust ("GLD"), iShares DJ US Real Estate Index Fund ("IYR"), MGM Mirage ("MGM"), Morgan Stanley ("MS"), Microsoft Corporation ("MSFT"), Micron Technology, Inc. ("MU"), Palm, Inc. ("PALM"), Petroleo Brasileiro S.A. ("PBR"), The Procter & Gamble Company ("PG"), Potash Corporation of Saskatchewan ("POT"), Transocean Ltd. ("RIG"), ProShares UltraShort S&P 500 ("SDS"), iShares Silver Trust ("SLV"), Energy Select Sector SPDR Fund ("XLE"), and Exxon Mobil Corporation ("XOM").

Other Fees

- Fees for orders executed in the Exchange's Facilitation, Solicited Order, Price Improvement and Block Order Mechanisms are for contracts that are part of the originating or contra order.
- Complex orders executed in the Facilitation and Solicited Order Mechanisms are charged fees only for the leg of the trade consisting of the most contracts.
- Payment for Order Flow fees will not be collected on transactions on QQQQ, BAC, C, SPY, IWM, XLF, AAPL, GE, JPM, INTC, GS, RIMM, T, VZ, UNG, FCX, CSCO, DIA, AMZN, X, AA, AIG, AXP, BBY, CAT, CHK, DNDN, EEM, EFA, EWZ, F, FAS, FAZ, FSLR, GDX, GLD, IYR, MGM, MS, MSFT, MU, PALM, PBR, PG, POT, RIG, SDS, SLV, XLE, and XOM options.[11]
- The Cancellation Fee will continue to apply in QQQQ, BAC, C, SPY, IWM, XLF, AAPL, GE, JPM, INTC, GS, RIMM, T, VZ, UNG, FCX, CSCO, DIA, AMZN, X, AA, AIG, AXP, BBY, CAT, CHK, DNDN, EEM, EFA, EWZ, F, FAS, FAZ, FSLR, GDX, GLD, IYR, MGM, MS, MSFT, MU, PALM, PBR, PG, POT, RIG, SDS, SLV, XLE, and XOM options.[12]
- The Exchange has a $0.20 per contract fee credit for members who, pursuant to Supplementary Material .02 to Rule 803, execute a transaction in the Exchange's flash auction as a response to orders from persons who are not broker/dealers and who are not Priority Customers.[13] For QQQQ, BAC, C, SPY, IWM, XLF, AAPL, GE, JPM, INTC, GS, RIMM, T, VZ, UNG, FCX, CSCO, DIA, AMZN, X, AA, AIG, AXP, BBY, CAT, CHK, DNDN, EEM, EFA, EWZ, F, FAS, FAZ, FSLR, GDX, GLD, IYR, MGM, MS, MSFT, MU, PALM, PBR, PG, POT, RIG, SDS, SLV, XLE, and XOM options, the Exchange proposes to lower the per contract fee credit for members who execute a transaction in the Exchange's flash auction as a response to orders from persons who are not broker/dealers and who are not Priority Customers to $0.10 per contract.
- The Exchange has a $0.20 per contract fee for market maker orders sent to the Exchange by EAMs.[14] Market maker orders sent to the Exchange by EAMs will be assessed a fee of $0.25 per contract for removing liquidity in QQQQ, BAC, C, SPY, IWM, XLF, AAPL, GE, JPM, INTC, GS, RIMM, T, VZ, UNG, FCX, CSCO, DIA, AMZN, X, AA, AIG, AXP, BBY, CAT, CHK, DNDN, EEM, EFA, EWZ, F, FAS, FAZ, FSLR, GDX, GLD, IYR, MGM, MS, MSFT, MU, PALM, PBR, PG, POT, RIG, SDS, SLV, XLE, and XOM options and $0.10 per contract for adding liquidity in QQQQ, BAC, C, SPY, IWM, XLF, AAPL, GE, JPM, INTC, GS, RIMM, T, VZ, UNG, FCX, CSCO, DIA, AMZN, X, AA, AIG, AXP, BBY, CAT, CHK, DNDN, EEM, EFA, EWZ, F, FAS, FAZ, FSLR, GDX, GLD, IYR, MGM, MS, MSFT, MU, PALM, PBR, PG, POT, RIG, SDS, SLV, XLE, and XOM options.

The Exchange has designated this proposal to be operative on June 1, 2010.

2. Statutory Basis

The basis under the Exchange Act for this proposed rule change is the requirement under Section 6(b)(4) that an exchange have an equitable

[9] Although these options classes will no longer be subject to the tiered market maker transaction fees, the volume from these options classes will continue to be used in the calculation of the tiers so that this new pricing does not affect a market maker's fee in all other names.

[10] The concept of incenting market makers with a rebate is not novel. In 2008, the CBOE established a program for its Hybrid Agency Liaison whereby it provides a $0.20 per contact rebate to its market makers provided that at least 80% of the market maker's quotes in a class during a month are on one side of the national best bid or offer. Market makers not meeting CBOE's criteria are not eligible to receive a rebate. *See* Securities Exchange Act Release No. 57231 (January 30, 2008), 73 FR 6752 (February 5, 2008). The CBOE has since lowered the criteria from 80% to 60%. *See* Securities Exchange Act Release No. 57470 (March 11, 2008), 73 FR 14514 (March 18, 2008).

[11] ISE currently has a payment-for-order-flow ("PFOF") program that helps the Exchange's market makers establish PFOF arrangements with an Electronic Access Member ("EAM") in exchange for that EAM preferencing some or all of its order flow to that market maker. This program is funded through a fee paid by Exchange market makers for each customer contract they execute, and is administered by both Primary Market Makers ("PMM") and Competitive Market Makers ("CMM"), depending to whom the order is preferenced.

[12] The Exchange assesses a Cancellation Fee of $2.00 to EAMs that cancel at least 500 orders in a month, for each order cancellation in excess of the total number of orders such member executed that month. All orders from the same clearing EAM executed in the same underlying symbol at the same price within a 300-second period are aggregated and counted as one executed order for purposes of this fee. This fee is charged only to customer orders.

[13] *See* Securities Exchange Act Release No. 61731 (March 18, 2010), 75 FR 14233 (March 24, 2010).

[14] *See* Securities Exchange Act Release No. 60817 (October 13, 2009), 74 FR 54111 (October 21, 2009).

allocation of reasonable dues, fees and other charges among its members and other persons using its facilities. The impact of the proposal upon the net fees paid by a particular market participant will depend on a number of variables, the most important of which will be its propensity to add or remove liquidity in QQQQ, BAC, C, SPY, IWM, XLF, AAPL, GE, JPM, INTC, GS, RIMM, T, VZ, UNG, FCX, CSCO, DIA, AMZN, X, AA, AIG, AXP, BBY, CAT, CHK, DNDN, EEM, EFA, EWZ, F, FAS, FAZ, FSLR, GDX, GLD, IYR, MGM, MS, MSFT, MU, PALM, PBR, PG, POT, RIG, SDS, SLV, XLE, and XOM options. The Exchange operates in a highly competitive market in which market participants can readily direct order flow to another exchange if they deem fee levels at a particular exchange to be excessive. The Exchange believes that the proposed fees it charges for options overlying QQQQ, BAC, C, SPY, IWM, XLF, AAPL, GE, JPM, INTC, GS, RIMM, T, VZ, UNG, FCX, CSCO, DIA, AMZN, X, AA, AIG, AXP, BBY, CAT, CHK, DNDN, EEM, EFA, EWZ, F, FAS, FAZ, FSLR, GDX, GLD, IYR, MGM, MS, MSFT, MU, PALM, PBR, PG, POT, RIG, SDS, SLV, XLE, and XOM remain competitive with fees charged by other exchanges and therefore continue to be reasonable and equitably allocated to those members that opt to direct orders to the Exchange rather than to a competing exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3) of the Act [15] and Rule 19b–4(f)(2) [16] thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form *(http://www.sec.gov/rules/sro.shtml);* or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–ISE–2010–57 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2010–57. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–ISE–2010–57 and should be submitted on or before July 15, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–15280 Filed 6–23–10; 8:45 am]

BILLING CODE 8010–01–P

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(2).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–62304; File No. SR–NYSEArca–2010–31]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Approving Proposed Rule Change To Amend NYSE Arca Rule 3.3(a) and Section 401(a) of the Exchange's Bylaws To Eliminate the Exchange's Audit Committee, Compensation Committee, and Regulatory Oversight Committee

June 16, 2010.

On April 20, 2010, NYSE Arca, Inc. ("NYSE Arca" or "Exchange") filed with the Securities and Exchange Commission ("Commission") pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend NYSE Arca Rule 3.3(a) and Section 401(a) of the Exchange's Bylaws to eliminate the Exchange's Audit Committee, Compensation Committee, and Regulatory Oversight Committee. The proposed rule change was published for comment in the **Federal Register** on May 11, 2010.[3] The Commission received no comments regarding the proposal. This order approves the proposed rule change.

I. Description of the Proposed Rule Change

Currently, the Board of Directors of the Exchange and its ultimate parent company, NYSE Euronext, each maintain its own Audit Committee and Compensation Committee. As more fully discussed in the Notice, the Exchange states that it has found that the work of these committees overlaps substantially.[4] As a result, the Exchange has proposed to revise its Bylaws to allow for the elimination of its Audit and Compensation Committees. In addition, the Exchange has proposed to eliminate its Regulatory Oversight Committee ("ROC"), and in lieu thereof, provide that the Board of NYSE

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 62032 (May 4, 2010), 75 FR 26304 ("Notice").

[4] *See Notice, supra* note 3.

Regulation, Inc. ("NYSER") [5] and the Board of the Exchange each will exercise a portion of the current responsibilities of the ROC, with the Board of the Exchange retaining ultimate legal responsibility for the regulation of its permit holders [6] and its market.[7]

II. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[8] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(1) of the Act,[9] which requires a national securities exchange to be so organized and have the capacity to carry out the purposes of the Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Act. The Commission also finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[10] in that it is designed, among other things, to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission has previously approved a structure in which certain committees of the Board of NYSE Euronext, including its Audit and Compensation Committees, were authorized to perform functions for subsidiaries of NYSE Euronext, including the New York Stock Exchange, LLC ("NYSE"),[11] and NYSE Amex, Inc. ("NYSE Amex").[12] The Commission has also previously approved a structure for NYSE Amex in which the Board of NYSER and the Board of NYSE Amex each exercise a portion of the Regulatory Oversight Committee responsibilities for NYSE Amex, with NYSE Amex retaining ultimate legal responsibility for the regulation of its permit holders and its market.[13]

The NYSE Arca Audit Committee. Under current Exchange Rule 3.3(a)(3)(B), the primary functions of the NYSE Arca Audit Committee are (i) to conduct an annual review with the independent auditors, to determine the scope of their examination and the cost thereof; (ii) to periodically review with the independent auditors and the internal auditor the Exchange's internal controls and the adequacy of the internal audit program; (iii) to review the annual reports submitted both internally and externally, and take such action with respect thereto as it may deem appropriate, and (iv) to recommend to the Board of NYSE Arca independent public accountants as auditors of the Exchange and its subsidiaries.

The NYSE Euronext Audit Committee is responsible under its charter for assessing the effectiveness of the internal audit function and reviewing with management and the independent auditor any major issues as to the adequacy of NYSE Euronext's internal risk management and internal controls, as well as meeting to review and discuss with management and the independent auditor NYSE Euronext's annual audited financial statements, quarterly financial statements prior to the filing of Form 10–Q, and significant financial reporting issues and judgments made in connection with the preparation of the financial statements.

In connection with this proposal, the Exchange represents that: (i) The specific responsibilities of the NYSE Euronext Audit Committee, as well as numerous others in its charter relating to oversight of both the independent and internal auditors, financial statement and disclosure matters, and corporate oversight, result in the responsibilities of the NYSE Arca Audit Committee being fully duplicated by the responsibilities of the NYSE Euronext Audit Committee; (ii) the NYSE Euronext Audit Committee will continue to be composed at all times of independent directors and will continue to review the financial condition of the Exchange as part of its oversight of the financial processes of NYSE Euronext and of each of its consolidated subsidiaries; (iii) NYSER has broad authority to oversee the regulatory activities of the Exchange and the other self-regulatory organizations whose ultimate parent is NYSE Euronext, through delegated authority and regulatory services agreements; (iv) it is the practice of NYSE Euronext's Global Risk and Audit Services Department ("RAS"), which performs internal audit functions, to report to the NYSER Board on all internal audit matters relating to the Exchange's regulatory responsibilities, and to ensure that NYSER has the appropriate authority to oversee RAS's activities with respect to the Exchange's regulatory responsibilities pursuant to the provisions of the RSA between the Exchange and NYSER; (v) RAS's written procedures will be amended to stipulate that the NYSER Board of Directors may, at any time, request that RAS conduct an audit of a matter of concern to it and report the results of the audit both to the NYSER Board of Directors and the NYSE Euronext Audit Committee; (vi) the chief regulatory officer of the Exchange would be in attendance at any meeting of the NYSER Board of Directors at which the results of any such audit would be reported by RAS; and (vii) the Exchange retains the authority to direct NYSER to request that RAS conduct such an audit of a matter of concern to it.

The Commission notes that the proposed elimination of the NYSE Arca Audit Committee is comparable to a structure for NYSE and NYSE Amex that the Commission has previously considered and approved.[14] The Commission finds that the proposed elimination of the NYSE Arca Audit and Compensation committees is consistent with the Act.

NYSE Arca Compensation Committee. The Exchange also proposes to eliminate its Compensation Committee, and to prescribe that the functions of that committee be performed by the NYSE Euronext Human Resources and Compensation Committee. Pursuant to current Exchange Rule 3.3(a)(4)(B), the NYSE Arca Compensation Committee is required to (i) review and approve corporate goals and objectives relevant to the Exchange CEO's compensation; (ii) evaluate the CEO's performance in light of those goals and objectives; (iii) set the CEO's compensation level based on this evaluation; and (iv) make recommendations to the Exchange's Board of Directors with respect to the design of incentive compensation and equity-based plans. As more fully set forth in the Notice, the Exchange represents that the NYSE Arca Compensation Committee's assigned responsibilities with respect to

[5] NYSER is a not-for-profit indirect subsidiary of NYSE Euronext.

[6] Permit holders at the Exchange are "members" of the Exchange as that term is defined in Section 3 of the Act.

[7] These arrangements are set forth in various regulatory services agreements. *See infra* note 16 and accompanying text.

[8] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[9] 15 U.S.C. 78f(b)(1).

[10] 15 U.S.C. 78f(b)(5).

[11] *See* Securities Exchange Act Release No. 55293 (February 14, 2007), 72 FR 8033 (February 22, 2007) (SR–NYSE–2006–120).

[12] *See* Securities Exchange Act Release No. 58673 (September 29, 2008), 73 FR 57707 (October 3, 2008) (SR–Amex–2008–62, SR–NYSE–2008–60) ("NYSE Amex Approval Order").

[13] *See id.*

[14] *See supra* notes 11 and 12.

compensation and personnel matters overlap with the broader mandate of the NYSE Euronext Human Resources and Compensation Committee. The Commission notes that the proposed elimination of the NYSE Arca Compensation Committee is comparable to a structure for NYSE and NYSE Amex that the Commission has previously considered and approved.[15] The Commission finds that the proposed elimination of the NYSE Arca Compensation Committees is consistent with the Act.

Elimination of NYSE Arca Regulatory Oversight Committee

The Exchange also proposes to eliminate its ROC, and in lieu thereof, provide for the exercise of the current formal responsibilities of the ROC to be divided between the NYSER Board and the Exchange's Board. Currently, the ROC is responsible for ensuring (i) the independence of Exchange regulation; (ii) adequate resources for the Exchange to properly fulfill its self-regulatory obligations; and (iii) that Exchange management fully supports the execution of the regulatory process.

In support of its proposal to eliminate the ROC, the Exchange represents that it has previously entered into an RSA with NYSER to perform all of the Exchange's regulatory functions on the Exchange's behalf; that the Financial Industry Regulatory Authority ("FINRA") performs some of the regulatory functions contracted out to NYSER pursuant to a separate multi-party regulatory services agreement with FINRA; [16] and that these regulatory contractual arrangements closely parallel the regulatory arrangements for NYSE Amex that the Commission reviewed and approved in the NYSE Amex Approval Order.[17] The Exchange states that the proposed elimination of its ROC will result in regulatory arrangements similar to those approved for NYSE Amex. In addition to the foregoing, the Exchange specifically represents that (i) NYSER will provide a comparable level of independence as that of a ROC; (ii) NYSE Euronext has agreed to provide adequate funding to NYSE Regulation to conduct its regulatory activities with respect to the Exchange; and (iii) notwithstanding its regulatory agreements, the Exchange retains ultimate legal responsibility for the regulation of its permit holders and its market and has full authority to take action to assure that its regulatory responsibilities are met. Acknowledging that it retains ultimate legal responsibility, the Exchange has further stated that its Board of Directors will directly assume the ROC's current formal responsibility to ensure that Exchange management fully supports the execution of the regulatory process and that it retains the authority to direct NYSER and FINRA to take any action necessary to fulfill the Exchange's statutory and self-regulatory obligations.

The Commission notes that the proposed elimination of the NYSE Arca ROC is comparable to the structure that the Commission approved in the NYSE Amex Approval Order.[18] The Commission finds that the proposed elimination of the NYSE Arca ROC is consistent with the Act.

III. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[19] that the proposed rule change (SR–NYSEArca–2010–31) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–15285 Filed 6–23–10; 8:45 am]

BILLING CODE 8010–01–P

[15] *See supra* note 12.

[16] The Commission notes that on June 14, 2010, NYSE, NYSER, NYSE Amex, and NYSE Arca ("NYSE Parties") entered into a new multi-party regulatory services agreement with FINRA, pursuant to which FINRA will perform additional regulatory functions on behalf of the NYSE Parties, including market surveillance and enforcement activities. *See http://www.nyse.com/press/1276509404802.html. See also* June 16, 2010 e-mail correspondence from William Love, Chief Counsel, NYSE Euronext, to Heidi Pilpel, Special Counsel, Commission.

[17] *See supra* note 12.

[18] *See supra* note 12.

[19] 15 U.S.C. 78s(b)(2).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–62312; File No. SR–NYSE–2010–20]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change Amending NYSE Rule 123C To Allow Exchange Systems To Provide Order Imbalance Information With Respect to Market At-The-Close and Marketable Limit At-the-Close Interest to Floor Brokers Beginning Two Hours and Until Fifteen Minutes Prior to the Scheduled Close of Trading on Every Trading Day

June 17, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") [1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on June 9, 2010, New York Stock Exchange LLC ("NYSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend proposes to amend [sic] NYSE Rule 123C ("The Closing Procedures") to describe the manner in which Exchange systems provide order imbalance information to Floor brokers. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.nyse.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The New York Stock Exchange LLC ("NYSE" or "Exchange") proposes to amend NYSE Rule 123C(6) to specify that, beginning at 2:00 p.m. on every trading day,[3] Floor brokers will receive an electronic communication from Exchange systems that provides the amount of, and any imbalance between, Market "At-The-Close" ("MOC") interest and marketable Limit "At-The-Close" ("LOC") interest to buy and MOC interest and marketable LOC interest to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] On any day that the scheduled close of trading on the Exchange is earlier than 4:00 p.m., the information will be disseminated beginning two hours prior to the scheduled close of trading.

sell in certain securities.[4] The MOC/LOC interest is executable only on the Close and is subject to cancellation at any time before 3:45 p.m.[5]

Background

Pursuant to NYSE Rule 115 ("Disclosure of Orders by DMMs"), DMMs may, while acting in a market making capacity, provide information about buying or selling interest in the market, including (a) Aggregated buying or selling interest contained in Floor broker agency interest files other than interest the broker has chosen to exclude from the aggregated buying and selling interest, (b) aggregated interest of Minimum Display Reserve Orders and (c) the interest included in DMM interest files, excluding CCS interest as described in Rule 1000(c), in response to an inquiry from a member conducting a market probe in the normal course of business. Market probes assist Floor brokers in representing customer orders efficiently and effectively. There is no limitation in Rule 115 as to the number of market probes permitted during the trading day.

Historically, Floor brokers could only orally request a market probe from the specialist.[6] As the NYSE evolved to a more automated trading venue, the Exchange and the Floor community endeavored to address an increase in the volume of market probes by Floor brokers to specialists in the afternoon hours leading up to the closing transaction. In May 2008, Exchange systems began electronically providing to Floor brokers, the amount of, and any imbalance between MOC interest and marketable LOC interest to buy and MOC interest and marketable LOC interest to sell in each security in which a Floor broker is representing an order or in any security that the Floor broker electronically requests such information. In March 2010, as part of changes to the Exchange's closing process, Exchange systems began decrementing the total imbalance between MOC interest and marketable LOC interest to buy and MOC interest and marketable LOC interest to sell by any Closing Offset Orders on the opposite side of the imbalance to calculate the imbalance (the "MOC/LOC imbalance information"). The dissemination of the MOC/LOC imbalance information to Floor brokers between 2:00 and 3:45 p.m. was deactivated on May 17, 2010. Floor brokers may still orally request and receive responses to market probes directly from DMMs.

Proposed Amendments to NYSE Rule 123C(6)

The Exchange proposes to amend NYSE Rule 123C(6) to state that, between 2 p.m. and 3:45 p.m. on any trading day (or two hours prior to the closing transaction until 15 minutes prior to the closing transaction on any day that the scheduled close of trading on the Exchange is earlier than 4 p.m.), Exchange systems shall automatically provide the MOC/LOC imbalance information to Floor brokers, approximately every 15 seconds, for any security in which the Floor broker is representing an order and in any security that the Floor broker specifically requests. Specific requests for information by Floor brokers will not carry over to the next trading day and must be re-entered on each trade date Floor brokers want to receive the information. Beginning at 3:45 p.m., Floor brokers may receive the Exchange's proprietary Order Information Imbalance datafeed pursuant to NYSE Rule 123C(6)(a)(iv). The Exchange provides the Order Information Imbalance datafeed to subscribers for a fee.

The Exchange's proposed dissemination of this MOC/LOC imbalance information is the electronic evolution of the market probe response that Floor brokers have always been entitled to receive and may otherwise orally request directly from DMMs. While a vast majority of the transactions executed on the Exchange are automated, Floor brokers play an important role for customers in those transactions that require the expertise of a professional trading floor agent. Providing the MOC/LOC imbalance information to Floor brokers is appropriate because a key component of their role as agent for these sophisticated customers is to provide market "color" to the extent permitted under applicable rules. The Exchange's electronic dissemination of this information would be limited to the Floor broker hand-held devices, which are unable to automatically forward or re-transmit the electronic datafeed to any other location, although Floor brokers are permitted to provide their customers with specific data points from the feed.[7]

Finally, the Exchange proposes to correct erroneous rule text in 123C(6)(a)(v). The rule text incorrectly states that the dissemination of the Order Imbalance Datafeed commences 10 minutes prior to the scheduled close of trading on any day that the scheduled close of trading on the Exchange is earlier than 4 p.m. The 10 minute interval is a legacy time frame related to the Exchange's prior publication of imbalance at 3:40 p.m. and 3:50 p.m. When the Exchange moved to a single imbalance publication at 3:45 p.m., the rule text should have been modified to reflect that dissemination of the Order Imbalance Information on any day that the scheduled close was prior to 4 p.m. would commence approximately 15 minutes before the scheduled closing time consistent with the single imbalance publication. The Exchange therefore seeks to amend NYSE Rule 123C(6)(a)(v) accordingly.

2. Statutory Basis

The basis under the Act for the proposed rule change is the requirement under Section 6(b)(5),[8] which requires that an exchange have rules that are designed to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The proposed rule change is consistent with these objectives in that the dissemination of MOC/LOC imbalance information would provide Floor brokers with an understanding of developing trends early enough to get appropriate direction from their customers and to know where on the physical Trading Floor it needs to deploy its brokers in preparation for the closing transaction. Overall, the Exchange believes that dissemination of MOC/LOC imbalance information to Floor brokers is consistent with the above objectives because it removes impediments to and perfects the mechanism of a free and open market through the efficient operation of the Exchange.

Dissemination of MOC/LOC imbalance information to Floor brokers would serve as an efficiency tool to

[4] The Exchange notes that parallel changes are proposed to the rules of its affiliate, NYSE Amex LLC. *See* SR–NYSEAmex–2010–25.

[5] *See* NYSE Rule 123C(3) and (9).

[6] The specialist is the predecessor to the DMM.

[7] Current NYSE rules permit a Floor broker to communicate information obtained through a market probe to a customer using a wired telephone line (NYSE Rule 36.20), an NYSE approved portable phone (NYSE Rule 36.21), or through a written electronic communication from the Floor brokers' hand-held device as permitted by the NYSE's "Wireless Data Communications Initiatives" (See Securities Exchange Act Release No. 59626 (March 25, 2009), 74 FR 14831 (April 1, 2009) (SR–NYSE–2009–33). The Exchange records all of the information sent to and transmitted from the hand-held devices.

[8] 15 U.S.C. 78f(b)(5).

enhance the Floor brokers' ability to meet their best execution obligations in the face of a dilemma that is unique to a physical Trading Floor, *i.e.,* how to position resources so that they are in the correct place to execute orders on behalf of sophisticated customers whose needs are not effectively met by strictly electronic trading. While the imbalance information is important to Floor brokers in carrying out their obligations to those customers, the Exchange believes this information would not be material to market participants executing automated orders. In this regard, the Exchange believes it is appropriate to provide Floor brokers with specific types of information that is directly related to the unique functions they perform on the Trading Floor.

In this particular case, the Exchange believes that the dissemination of MOC/LOC information to Floor brokers would promote the efficient operation of the Exchange's market by reducing the frequency of time-consuming Floor broker oral market probes leading up to the closing transaction, thus affording DMMs more time to monitor trading. As trading has become more electronic, staffing on the trading Floor has declined, so that there are now fewer Floor brokers even as the number of listed securities has increased.[9] Similarly, DMM units and individual DMMs on the Floor are managing trading in greater numbers of stocks than ever before. The need for DMMs to be focused on their assigned securities, particularly on high volume trading days, such as an Expiration Friday or an index rebalancing event, or trading days with high levels of market volatility, is critical to the maintenance of fair and orderly markets.[10]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2010–20 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2010–20. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2010–20 and should be submitted on or before July 15, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–15246 Filed 6–23–10; 8:45 am]

BILLING CODE 8010–01–P

[9] The number of Floor brokers operating on the Exchange Floor has decreased since 2004 from approximately 800 Floor brokers to approximately 325 Floor brokers operating on the Floor today.

[10] It should be noted that NYSE rules and the Federal securities laws provide safeguards that are designed to deter the potential abuse of market probe information. For example, Floor broker member organizations are not permitted to initiate proprietary orders on the Floor. In addition, Floor brokers representing a principal or proprietary order that has been initiated in the off-Floor premises of the firm are subject to the requirements of Section 11(a) of the Securities Exchange Act of 1934.

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–62311; File No. SR–NYSEAmex–2010–25]

Self-Regulatory Organizations; NYSE Amex LLC; Notice of Filing of Proposed Rule Change Amending NYSE Amex Rule 123C To Allow Exchange Systems To Provide Order Imbalance Information With Respect to Market At-the-Close and Marketable Limit At-the-Close Interest to Floor Brokers Beginning Two Hours and Until Fifteen Minutes Prior to the Scheduled Close of Trading on Every Trading Day

June 17, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") [1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on June 9, 2010, NYSE Amex LLC ("NYSE Amex" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE Amex Rule 123C ("The Closing Procedures") to describe the manner in which Exchange systems provide order imbalance information to Floor brokers. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.nyse.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

NYSE Amex LLC ("NYSE Amex" or "Exchange") proposes to amend NYSE Amex Rule 123C(6) to specify that, beginning at 2:00 p.m. on every trading day,[3] Floor brokers will receive an electronic communication from Exchange systems that provides the amount of, and any imbalance between, Market "At-The-Close" ("MOC") interest and marketable Limit "At-The-Close" ("LOC") interest to buy and MOC interest and marketable LOC interest to sell in certain securities.[4] The MOC/LOC interest is executable only on the Close and is subject to cancellation at any time before 3:45 p.m.[5]

Background

Pursuant to NYSE Amex Rule 115 ("Disclosure of Orders by DMMs"), DMMs may, while acting in a market making capacity, provide information about buying or selling interest in the market, including (a) Aggregated buying or selling interest contained in Floor broker agency interest files other than interest the broker has chosen to exclude from the aggregated buying and selling interest, (b) aggregated interest of Minimum Display Reserve Orders and (c) the interest included in DMM interest files, excluding CCS interest as described in Rule 1000(c), in response to an inquiry from a member conducting a market probe in the normal course of business. Market probes assist Floor brokers in representing customer orders efficiently and effectively. There is no limitation in Rule 115 as to the number of market probes permitted during the trading day.

Historically, Floor brokers could only orally request a market probe from the specialist.[6] As the NYSE Amex evolved to a more automated trading venue, the Exchange and the Floor community endeavored to address an increase in the volume of market probes by Floor brokers to specialists in the afternoon hours leading up to the closing transaction. In May 2008, Exchange systems began electronically providing to Floor brokers, the amount of, and any imbalance between MOC interest and marketable LOC interest to buy and MOC interest and marketable LOC interest to sell in each security in which a Floor broker is representing an order or in any security that the Floor broker electronically requests such information. In March 2010, as part of changes to the Exchange's closing process, Exchange systems began decrementing the total imbalance between MOC interest and marketable LOC interest to buy and MOC interest and marketable LOC interest to sell by any Closing Offset Orders on the opposite side of the imbalance to calculate the imbalance (the "MOC/LOC imbalance information"). The dissemination of the MOC/LOC imbalance information to Floor brokers between 2 and 3:45 p.m. was deactivated on May 17, 2010. Floor brokers may still orally request and receive responses to market probes directly from DMMs.

Proposed Amendments to NYSE Amex Rule 123C(6)

The Exchange proposes to amend NYSE Amex Rule 123C(6) to state that, between 2:00 p.m. and 3:45 p.m. on any trading day (or two hours prior to the closing transaction until 15 minutes prior to the closing transaction on any day that the scheduled close of trading on the Exchange is earlier than 4 p.m.), Exchange systems shall automatically provide the MOC/LOC imbalance information to Floor brokers, approximately every 15 seconds, for any security in which the Floor broker is representing an order and in any security that the Floor broker specifically requests. Specific requests for information by Floor brokers will not carry over to the next trading day and must be re-entered on each trade date Floor brokers want to receive the information. Beginning at 3:45 p.m., Floor brokers may receive the Exchange's proprietary Order Information Imbalance datafeed pursuant to NYSE Amex Rule 123C(6)(a)(iv). The Exchange provides the Order Information Imbalance datafeed to subscribers for a fee.

The Exchange's proposed dissemination of this MOC/LOC imbalance information is the electronic evolution of the market probe response that Floor brokers have always been entitled to receive and may otherwise orally request directly from DMMs. While a vast majority of the transactions executed on the Exchange are automated, Floor brokers play an important role for customers in those transactions that require the expertise of a professional trading floor agent. Providing the MOC/LOC imbalance information to Floor brokers is appropriate because a key component of their role as agent for these sophisticated customers is to provide market "color" to the extent permitted under applicable rules. The Exchange's electronic dissemination of this information would be limited to the Floor broker hand-held devices, which are unable to automatically forward or re-transmit the electronic datafeed to any other location, although Floor brokers are permitted to provide their customers with specific data points from the feed.[7]

Finally, the Exchange proposes to correct erroneous rule text in 123C(6)(a)(v). The rule text incorrectly states that the dissemination of the Order Imbalance Datafeed commences 10 minutes prior to the scheduled close

[3] *See* e-mail from Theodore R. Lazo, NYSE Euronext, to Steve Kuan, Securities and Exchange Commission, on June 16, 2010 ("June 16, 2010 e-mail"). On any day that the scheduled close of trading on the Exchange is earlier than 4:00 p.m., the information will be disseminated beginning two hours prior to the scheduled close of trading.

[4] The Exchange notes that parallel changes are proposed to the rules of its affiliate, the New York Stock Exchange LLC. *See* SR–NYSE–2010–20 and June 16, 2010 e-mail.

[5] *See* NYSE Rule 123C(3) and (9).

[6] The specialist is the predecessor to the DMM.

[7] Current NYSE Amex rules permit a Floor broker to communicate information obtained through a market probe to a customer using a wired telephone line (NYSE Amex Rule 36.20), an NYSE Amex approved portable phone (NYSE Amex Rule 36.21), or through a written electronic communication from the Floor brokers' hand-held device as permitted by the NYSE Amex's "Wireless Data Communications Initiatives" (*See* Securities Exchange Act Release No. 59627 (March 25, 2009), 74 FR 14834 (April 1, 2009) (SR–NYSEAmex–2009–02). *See* June 16, 2010 e-mail. The Exchange records all of the information sent to and transmitted from the hand-held devices.

of trading on any day that the scheduled close of trading on the Exchange is earlier than 4 p.m. The 10 minute interval is a legacy time frame related to the Exchange's prior publication of imbalance at 3:40 p.m. and 3:50 p.m. When the Exchange moved to a single imbalance publication at 3:45 p.m., the rule text should have been modified to reflect that dissemination of the Order Imbalance Information on any day that the scheduled close was prior to 4 p.m. would commence approximately 15 minutes before the scheduled closing time consistent with the single imbalance publication. The Exchange therefore seeks to amend NYSE Amex Rule 123C(6)(a)(v) accordingly.

2. Statutory Basis

The basis under the Act for the proposed rule change is the requirement under Section 6(b)(5),[8] which requires that an exchange have rules that are designed to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The proposed rule change is consistent with these objectives in that the dissemination of MOC/LOC imbalance information would provide Floor brokers with an understanding of developing trends early enough to get appropriate direction from their customers and to know where on the physical Trading Floor it needs to deploy its brokers in preparation for the closing transaction. Overall, the Exchange believes that dissemination of MOC/LOC imbalance information to Floor brokers is consistent with the above objectives because it removes impediments to and perfects the mechanism of a free and open market through the efficient operation of the Exchange.

Dissemination of MOC/LOC imbalance information to Floor brokers would serve as an efficiency tool to enhance the Floor brokers' ability to meet their best execution obligations in the face of a dilemma that is unique to a physical Trading Floor, i.e., how to position resources so that they are in the correct place to execute orders on behalf of sophisticated customers whose needs are not effectively met by strictly electronic trading. While the imbalance information is important to Floor brokers in carrying out their obligations to those customers, the Exchange believes this information would not be material to market participants executing automated orders. In this regard, the Exchange believes it is appropriate to provide Floor brokers with specific types of information that is directly related to the unique functions they perform on the Trading Floor.

In this particular case, the Exchange believes that the dissemination of MOC/LOC information to Floor brokers would promote the efficient operation of the Exchange's market by reducing the frequency of time-consuming Floor broker oral market probes leading up to the closing transaction, thus affording DMMs more time to monitor trading. As trading has become more electronic, staffing on the trading Floor has declined, so that there are now fewer Floor brokers even as the number of listed securities has increased.[9] Similarly, DMM units and individual DMMs on the Floor, are managing trading in greater numbers of stocks than ever before. The need for DMMs to be focused on their assigned securities, particularly on high volume trading days, such as an Expiration Friday or an index rebalancing event, or trading days with high levels of market volatility, is critical to the maintenance of fair and orderly markets.[10]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSEAmex–2010–25 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAmex–2010–25. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the

[8] 15 U.S.C. 78f(b)(5).

[9] The number of Floor brokers operating on the Exchange Floor has decreased since 2004 from approximately 800 Floor brokers to approximately 325 Floor brokers operating on the Floor today.

[10] It should be noted that NYSE rules and the Federal securities laws provide safeguards that are designed to deter the potential abuse of market probe information. For example, Floor broker member organizations are not permitted to initiate proprietary orders on the Floor. In addition, Floor brokers representing a principal or proprietary order that has been initiated in the off-Floor premises of the firm are subject to the requirements of Section 11(a) of the Securities Exchange Act of 1934.

Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAmex–2010–25 and should be submitted on or before July 15, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–15245 Filed 6–23–10; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–62301; File No. SR–ISE–2010–49]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Related to Do-Not-Route Orders

June 16, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Exchange Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 14, 2010, the International Securities Exchange, LLC (the "Exchange" or the "ISE") filed with the Securities and Exchange Commission (the "SEC" or the "Commission") the proposed rule change as described in Items I, II, and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt a do-not-route order type. The text of the rule amendment is as follows (additions are *in italics*):

Rule 715. Types of Orders

(a) through (l) no change.

(m) *Do-Not-Route Orders. A do-not-route order is a market or limit order that is to be executed in whole or in part on the Exchange only. Due to prices available on another options exchange (as provided in Chapter 19 (Order Protection; Locked and Crossed Markets)), any balance of a do-not-route order that cannot be executed upon entry, or placed on the Exchange's limit order book, will be automatically cancelled.*

Supplementary Material to Rule 715

.01 no change.

* * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) *Purpose*—The Exchange's rules related to intermarket linkage provide, among other things, that transactions not be executed at prices that are inferior to the national best bid or offer (the "trade-through rule").[3] Currently, the Exchange cancels marketable non-customer orders that cannot be executed because its prices are inferior to the national best bid or offer, while such marketable customer orders are presented to the primary market maker for handling.[4] The Exchange is proposing to adopt a do-not-route order so that customers may indicate that they want their orders canceled if they are marketable, but not executable on the Exchange. If a customer order is not marked as a do-not-route order, it would continue to be presented to the primary market maker for handling if it is marketable but not executable on the Exchange. A do-not-route order is a market or limit order. This order type is commonly offered on other exchanges.[5]

(2) *Basis*—The basis under the Securities Exchange Act of 1934 ("Exchange Act") for this proposed rule change is the requirement under Section 6(b)(5) that an exchange have rules that are designed to promote just and equitable principles of trade, and to remove impediments to and perfect the mechanism for a free and open market and a national market system, and in general, to protect investors and the public interest. In particular, the proposal will give customers greater control over where their orders are executed if they so choose.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[6] and Rule 19b–4(f)(6) thereunder.[7]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

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[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] ISE Rule 1901 (Order Protection).

[4] ISE Rule 714 (Automatic Execution of Orders).

[5] *E.g.,* NYSE Arca Rule 6.62(p) (PNP Orders are not routable orders); NASDAQ OMX PHLX Rule 1066(c)(8) (Immediate or Cancel Orders are not routable orders); and CBOE Rule 6.53(s) (CBOE Only orders are not routable orders).

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the self-regulatory organization to submit to the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–ISE–2010–49 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2010–49. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2010–49 and should be submitted on or before July 15, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–15242 Filed 6–23–10; 8:45 am]

BILLING CODE 8011–01–P

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–62323; File No. SR–C2–2010–002]

Self-Regulatory Organizations; C2 Options Exchange, Incorporated; Order Granting Approval of a Proposed Rule Change Relating to the Corporate Restructuring of C2 in Connection With the Demutualization of the Chicago Board Options Exchange, Incorporated

June 17, 2010.

I. Introduction

On May 14, 2010, pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] C2 Options Exchange, Incorporated ("C2") filed with the Securities and Exchange Commission ("Commission") a proposed rule change relating to its corporate structure in connection with the plan of its parent company, the Chicago Board Options Exchange, Incorporated ("CBOE"), to restructure from a Delaware non-stock corporation to a Delaware stock corporation that would be a wholly-owned subsidiary of CBOE Holdings, Inc. ("CBOE Holdings"), a holding company organized as a Delaware stock corporation ("CBOE Demutualization").[3] The proposed rule change was published for comment in the **Federal Register** on May 25, 2010.[4] The Commission received no comments on the proposal.

II. Discussion and Commission Findings

After careful review of the proposal, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[5] In particular, as discussed in more detail below, the Commission finds that the proposed rule change is consistent with Section 6(b) of the Act[6] in general, and furthers the objectives of Section 6(b)(1) of the Exchange Act,[7] in particular, in that it enables C2 to be so organized as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the rules of C2. The Commission also finds that this filing furthers the objectives of Section 6(b)(5) of the Act insofar as it would result in an exchange governance structure designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.[8] In particular, the Commission believes that the Certificate of Incorporation and Bylaws of CBOE Holdings and C2 are designed to protect and maintain the integrity of the self-regulatory functions of C2 and to allow it to carry out it regulatory responsibilities under the Act.

C2 is currently a wholly-owned subsidiary of CBOE.[9] When the corporate restructuring in connection with the CBOE Demutualization is complete, CBOE will become a wholly-owned subsidiary of CBOE Holdings. At the same time, C2 has proposed to become a wholly-owned subsidiary CBOE Holdings by having CBOE dividend-up to CBOE Holdings all of the shares of C2.[10] Consequently, after the corporate restructuring in connection with the CBOE Demutualization is completed, CBOE Holdings would hold all of the outstanding common stock of *both* C2 and CBOE, as well as certain other entities that are currently

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 62158 (May 24, 2010), 75 FR 30082 (May 28, 2010) (SR–CBOE–2008–88) (order approving the CBOE Demutualization).

[4] *See* Securities Exchange Act Release No. 62118 (May 18, 2010), 75 FR 29375.

[5] In approving the proposed rule change, the Commission has considered its impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(1).

[8] 15 U.S.C. 78f(b)(5).

[9] *See* Securities Exchange Act Release No. 61152 (December 10, 2009), 74 FR 66699 (December 16, 2009) (File No. 10–191) (order approving the application of C2 for registration as a national securities exchange). *See also* Securities Exchange Act Release No. 61140 (December 10, 2009), 74 FR 67294 (December 18, 2009) (SR–CBOE–2009–048) (order approving a proposed rule change regarding authority over C2 Options Exchange, Incorporated).

[10] After the restructuring, the owners of membership interests in CBOE will become stockholders of CBOE Holdings through the conversion of their memberships into shares of common stock of CBOE Holdings. In addition, members of the settlement class in the lawsuit brought by The Board of Trade of the City of Chicago, Inc., its parent company, CME Group, Inc., and a class of individuals (collectively, the "CBOT Parties") against CBOE and CBOE's board of directors will become stockholders of CBOE Holdings. *CME Group Inc. et al.* v. *CBOE Inc. et al.,* Civil Action No. 2369–VCN (Filed Aug. 23, 2006). CBOE entered into a Stipulation of Settlement ("Stipulation") on August 20, 2008 with the CBOT Parties to resolve this lawsuit. The Stipulation and amendments to it can be found at (*http://www.cboe.org/Legal/*).

subsidiaries of CBOE.[11] C2 and CBOE, however, would continue to be separately registered national securities exchanges under Section 6 of the Act[12] and would continue to operate their exchange businesses and facilities.

The Commission recently approved C2's registration as a national securities exchange and, in that context, approved C2's Certificate of Incorporation and Bylaws.[13] In connection with its currently proposed corporate restructuring, C2 does not propose any significant changes to these governing documents but does propose, as discussed further below, to make certain changes to its Certificate of Incorporation to effect the change of ownership of C2 from CBOE to CBOE Holdings, to clarify certain aspects of C2's Bylaws as a result of this transfer of ownership, and to make certain ministerial changes to C2's Certificate of Incorporation and Bylaws.

CBOE Holdings

As mentioned above, C2 is now proposing a corporate restructuring that would transfer ownership of C2 from CBOE to CBOE Holdings. C2 is not proposing any changes to the governing documents of CBOE Holdings, which already contemplate the ownership by CBOE Holdings of one or more self-regulatory organizations ("SRO") (*e.g.,* CBOE and C2) (the "Regulated Securities Exchange Subsidiaries").[14] Consequently, CBOE Holdings' Certificate of Incorporation and Bylaws approved by the Commission in connection with the CBOE Demutualization will continue to govern the activities of CBOE Holdings.

Although CBOE Holdings is not itself an SRO, its activities with respect to the operation of any SRO subsidiary, including C2, must be consistent with, and must not interfere with, the self-regulatory obligations of that SRO subsidiary. To this end, certain provisions of CBOE Holdings' Certificate of Incorporation and the Bylaws are designed to ensure that C2, though a wholly-owned subsidiary of CBOE Holdings, is able to maintain the independence of its self-regulatory function and operate unencumbered in a manner that complies with the federal securities laws, and, along with the Commission, is able to fulfill its regulatory and oversight obligations under the Act.

Specifically, the Certificate of Incorporation of CBOE Holdings provides that CBOE Holdings, its officers, directors, employees, and agents must irrevocably submit to the jurisdiction of the United States federal courts, the Commission, and the Regulated Securities Exchange Subsidiaries[15] for the purposes of any suit, action or proceeding pursuant to the United States federal securities laws, and the rules and regulations thereunder, commenced or initiated by the Commission arising out of, or relating to, the Regulated Securities Exchange Subsidiaries' activities.[16] Further, so long as CBOE Holdings controls any Regulated Securities Exchange Subsidiaries, the books, records, premises, officers, directors, and employees of CBOE Holdings is deemed to be the books, records, premises, officers, directors, and employees of the Regulated Securities Exchange Subsidiary for purposes of and subject to oversight pursuant to the Act to the extent that they relate to the business of such Regulated Securities Exchange Subsidiary.[17] In addition, all confidential information pertaining to the self-regulatory function of Regulated Securities Exchange Subsidiaries contained in the books and records of an exchange that comes into the possession of CBOE Holdings must not be made available to any persons other than to those officers, directors, employees and agents of CBOE Holdings that have a reasonable need to know the contents thereof, be retained in confidence by CBOE Holdings and the officers, directors, employees and agents of CBOE Holdings, and not be used for any commercial purposes.[18] CBOE Holdings Certificate of Incorporation also contains a provision requiring each director of the CBOE Holdings board to take into consideration the effect that CBOE Holdings' actions would have on CBOE's ability to carry out its responsibilities under the Act.[19] Pursuant to the CBOE Holdings Certificate of Incorporation, for so long as CBOE Holdings controls any Regulated Securities Exchange Subsidiary, each officer, director and employee of CBOE Holdings must give due regard to the preservation of the independence of the self-regulatory function of the Regulated Securities Exchange Subsidiaries and to their obligations under the Exchange Act.[20] Finally, CBOE Holdings Certificate of Incorporation provides that for so long as CBOE Holdings controls any Regulated Securities Exchange Subsidiary, before any amendment, alteration or repeal of any provision of the Certificate of Incorporation and Bylaws of CBOE Holdings becomes effective, such amendment, alteration or repeal will be submitted to the board of directors of each Regulated Securities Exchange Subsidiary, and if such amendment, alteration or repeal must be filed with or filed with and approved by the Commission, then such amendment, alteration or repeal will not become effective until filed with or filed with and approved by the Commission, as the case may be.[21]

In approving the CBOE Demutualization and permitting CBOE Holdings to wholly own CBOE, the Commission noted that the governing documents of CBOE Holdings are designed to facilitate Regulated Securities Exchange Subsidiaries' ability to fulfill their self-regulatory obligations and are, therefore, consistent with the Act.[22] C2's proposal to become a wholly-owned subsidiary of CBOE Holdings is identical to the SRO ownership structure the Commission approved in the CBOE Demutualization

[11] These subsidiaries are: CBOE Futures Exchange, LLC, which operates an electronic futures exchange; Chicago Options Exchange Building Corporation, which owns the building in which CBOE operates; CBOE, LLC, which holds a 24.01% interest in OneChicago, LLC, a security futures exchange; CBOE II, LLC, which has no assets or activities; DerivaTech Corporation, which owns certain educational software; Market Data Express, LLC, which distributes various types of market data; and The Options Exchange, Incorporated, which currently has no assets or activities.

[12] 15 U.S.C. 78f.

[13] *See* Securities Exchange Act Release No. 61152, *supra* note 9.

[14] *See infra* note 15 (discussing the term "Regulated Securities Exchange Subsidiary").

[15] "Regulated Securities Exchange Subsidiary" means any national securities exchange controlled, directly or indirectly, by the Corporation, including, but not limited to CBOE. *See* Article Fifth(xi) of the CBOE Holdings Certificate of Incorporation. Thus, C2 as a registered national securities exchange would fit within the definition of a Regulated Securities Exchange Subsidiary.

[16] *See* Article Fourteen of the CBOE Holdings Certificate of Incorporation.

[17] The books and records of CBOE Holdings relating to the business of a Regulated Securities Exchange Subsidiary is subject at all times to inspection and copying by the Commission and the Regulated Securities Exchange Subsidiary. *See* Article Fifteen of the CBOE Holdings Certificate of Incorporation. In addition, the CBOE Holdings Bylaws provide that the books of CBOE Holdings must be kept within the United States. *See* Section 1.3 of the CBOE Holdings Bylaws.

[18] Notwithstanding this restriction, nothing in the CBOE Holdings Certificate of Incorporation is to be interpreted so as to limit or impede the rights of the Commission or CBOE to access and examine such confidential information or to limit or impede the ability of any officers, directors, employees or agents of CBOE Holdings to disclose such confidential information to the Commission or CBOE. *See* Article Fifteen of the CBOE Holdings Certificate of Incorporation.

[19] *See* Article Sixteen(d) of the CBOE Holdings Certificate of Incorporation.

[20] *See* Article Sixteen(c) of the CBOE Holdings Certificate of Incorporation.

[21] *See* Article Eleven of the CBOE Holdings Certificate of Incorporation and Section 10.2 of the CBOE Holdings Bylaws.

[22] *See supra* note 3.

and does not raise any new regulatory issues. Consistent with its approval of the CBOE Demutualization, the Commission similarly believes that the governing documents of CBOE Holdings are designed to protect the independence of the self-regulatory function of a wholly-owned C2, enable C2 to operate in a manner that complies with the Federal securities laws, and facilitate the ability of C2 and the Commission to fulfill their regulatory and oversight obligations under the Act.[23]

C2

Although CBOE Holdings would replace CBOE as the parent company and sole shareholder of C2, C2 would continue to be registered as a national securities exchange under Section 6 of the Exchange Act. In this respect, certain provisions of C2's Certificate of Incorporation and Bylaws are designed to enable C2 to carry out the purposes of the Act and to comply and enforce compliance by its members and persons associated with its members with all applicable rules and regulations.[24]

As noted above, C2 does not propose any significant changes to its governing documents but does propose to make certain changes to its Certificate of Incorporation to effect the change of ownership of C2 from CBOE to CBOE Holdings, to clarify certain aspects of C2's Bylaws as a result of this transfer of ownership, and to make certain ministerial changes to C2's Certificate of Incorporation and Bylaws. Namely, C2 proposes to amend its Certificate of Incorporation in connection with the transfer of ownership of all of the common stock of C2 from CBOE to CBOE Holdings and to require Commission approval if CBOE Holdings sells, transfers, or assigns any shares of C2 common stock.[25] In addition, C2 proposes a number of other changes to reflect and generally conform to the most recent version of the corresponding governing documents of CBOE that were approved by the Commission in connection with the CBOE Demutualization. These changes include amending C2's Bylaws to provide that all directors of the C2 board would serve one-year terms, rather than staggered two-year terms [26] and to remove a reference to electing a class of directors; [27] amending its Bylaws to provide that Representative Directors (as opposed to any Director) may be removed for cause by the holders of a majority of the shares of stock then entitled to vote at an election of directors; [28] and amending its Bylaws to provide that the C2 Regulatory Oversight Committee would consist of at least three directors instead of at least four directors.[29] Finally, because the rules of C2 use terms from the CBOE rules, and also incorporate by reference certain CBOE rules, C2 also proposes to make minor, non-substantive changes to its rules to reflect the changes in terminology and other technical changes that CBOE plans to make to its rules in connection with the CBOE Demutualization.[30]

C2 currently has in place a voting agreement with CBOE in which CBOE agrees to vote in favor of those individuals nominated by C2's Nominating and Governance Committee for election as C2 Representative Directors. After the demutualization, CBOE Holdings, and not CBOE, would be the sole stockholder of C2. Accordingly, C2 has proposed to enter into a new voting agreement with CBOE Holdings that similarly would require CBOE Holding to vote in favor of those individuals nominated by C2's Nominating and Governance Committee for election as C2 Representative Directors. In addition, C2 proposes to add a provision in the voting agreement to reflect the "for cause" removal standard for Representative Directors in C2's Bylaws, as discussed above.

The Commission notes that changes proposed by C2 in its governing documents and rules are mostly technical in nature. Further, the Commission notes that C2's proposed amendment to require the removal of Representative Directors, rather than any director, for cause by the holders of a majority of the shares of stock is consistent with provisions approved by the Commission for other SROs'

[23] The Commission also notes that the Certificate of Incorporation of CBOE Holdings places certain ownership and voting limits on the holders of CBOE Holdings stock and their Related Persons. These restrictions are intended to address the possibility that a person holding a controlling interest in an SRO could use that interest to affect the SRO's regulatory responsibilities under the Act. In particular, these restrictions provide that no person, either alone or together with its Related Persons, may own directly or indirectly more than 10% of the CBOE Holdings or more than 20% in the event a public offering of the CBOE Holdings. Further, no person, either alone or together with its Related Persons, will be entitled to vote more than 10% of the CBOE Holdings common interest or more than 20% in the event a public offering of the CBOE Holdings. *See* Article Six(a) and (b) of the CBOE Holdings Certificate of Incorporation.

[24] For example, C2's current board composition is designed to be comparable to the board compositions the Commission has approved for other SROs. Namely, the number of Non-Industry Directors on C2 board must equal or exceed the sum of the number of Industry Directors and the number of Industry Directors must equal or exceed 30% of the board. Further, at least 20% of the directors on the board must be nominated (or otherwise selected by a petition of C2 members) by the Industry-Director Subcommittee of the Nominating and Governance Committee (such directors, "Representative Directors"). *See* Section 3.1 of the C2 Bylaws. For definitions of "Non-Industry Directors" and "Industry Directors," *see* Section 3.1 of the C2 Bylaws. For the definition of "Industry-Director Subcommittee of the Nominating and Governance Committee," *see* Section 3.2 of the C2 Bylaws. Further, C2 has a Regulatory Oversight Committee ("ROC") that monitors its regulatory operations. *See* Section 4.6 of C2 Bylaws.

[25] *See* Article Four of the C2 Certificate of Incorporation. In addition, C2 proposes to delete Article Twelve of the Certificate of Incorporation because it is no longer necessary.

[26] *See* Section 3.1 of the C2 Bylaws. Further, C2 proposes to delete the second sentence of Section 3.1, which provides that "[t]he Board shall initially consist of 23 directors, including the Chief Executive Officer, twelve Non-Industry Directors and ten Industry Directors," because the initial board of directors of C2 has already been appointed. C2 also proposes to change the reference to the "Board of the Corporation" in Section 3.1 to the "Board" and to delete a reference in the last sentence of the first paragraph regarding the initial C2 Board, because that Board has already been appointed.

[27] *See* Section 3.2 of the C2 Bylaws. C2 would no longer have different classes of directors.

[28] *See* Section 3.4(c) of the C2 Bylaws. C2 also proposes to amend Section 3.4(c) to replace a reference to "SEC" with "Securities and Exchange Commission ("SEC")." In addition, C2 proposes to move a reference to "Representative Directors" (described below) in the first sentence of the seventh paragraph of Section 3.1 of the C2 Bylaws to clarify the intent of that sentence.

[29] *See* Section 4.6 of the C2 Bylaws. C2 also proposes to amend Section 5.8 of the Bylaws to modify the responsibilities of the Treasurer of C2. Specifically, C2 is proposing to delete the second sentence in Section 5.8, which reads "[i]n addition, the Treasurer shall perform such duties and have such powers that are incident to the office of Treasurer, including without limitation the duty to keep and be responsible for all funds of the Corporation," to make this section consistent with the Treasurer provision in CBOE's post-demutualization Bylaws.

[30] For example, CBOE is replacing the term "member" (or variations of it) with the term "Trading Permit Holder" (or variations of it) throughout its rulebook in connection with its demutualization. Similarly, C2 proposes to replace references in its rules to a CBOE "member" with the term "CBOE Trading Permit Holder" (or "Trading Permit Holder" in certain instances where there is a direct cross-reference to CBOE rules). Further, C2 proposes to adopt in C2 Rule 1.1 the term "CBOE Trading Permit," which is defined as a "Trading Permit" as such term is defined in CBOE's Bylaws and rules, and the term "CBOE Trading Permit Holder," which is defined as a "Trading Permit Holder" as such term is defined in CBOE's Bylaws and rules. C2 also proposes to replace the term CBOE "membership" with the term "CBOE Trading Permit" (or "Trading Permit" in certain instances where there is a direct cross-reference to CBOE rules) and a CBOE "Clearing Member" (or variations of it) with the term "Clearing Trading Permit Holder." In addition, C2 proposes to make a few minor, non-substantive fixes to its rules. For example, C2 proposes to replace references to a C2 "member" in its rules with the term "Permit Holder" or "Participant" (which both have the same meaning under C2 rules). C2 also proposes to delete a reference in C2 Rule 3.3(b) regarding member organizations not registered as broker-dealers, because C2 does not have such organizations (*i.e.,* all Permit Holders of C2 are required to be registered as broker-dealers). In addition, C2 proposes to fix some of the cross-references in its rules to CBOE rules.

governing documents.[31] Moreover, as the ROC would continue to be composed solely of Non-Industry Directors, the Commission does not believe C2's proposal to decreased size of the committee compromises its ability to monitor the adequacy and effectiveness of C2's regulatory program. Finally, the Commission believes that a new voting agreement, as proposed by C2, is appropriate to ensure that C2 meet its statutory obligation to provide for the fair representation of its members in the administration of C2.[32] As the Commission has previously noted in the context of other exchange governance proposals, this requirement helps to ensure that an exchange's members have a voice in the governing body of the exchange and the corresponding exercise by the exchange of its self-regulatory authority, and that the exchange is administered in a way that is equitable to all who trade on its market or through its facilities.[33]

III. Conclusion

For the foregoing reasons, the Commission believes that the proposed rule changes in connection with the transfer of ownership of C2 from CBOE to CBOE Holdings is consistent with the Act and that C2 will be so organized and have the capacity to be able to carry out the purposes of the Act. The provisions in the applicable governing documents, discussed above, should minimize the potential that any person could interfere with or restrict the ability of C2 or the Commission to effectively carry out their respective regulatory oversight responsibilities. Further, the Commission notes that CBOE Holding has undertaken to ensure and maintain the regulatory independence of C2 to enable C2 to operate in a manner that complies with the federal securities laws, including the objectives of Sections 6(b) of the Act.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[34] that the proposed rule change (SR–C2–2010–002) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[35]

Florence E. Harmon,

Deputy Secretary.

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[31] *See, e.g.,* Section 7 of the Amended and Restated By-Laws of BATS Exchange, Inc. and Section 7 of the Amended and Restated Bylaws of EDGX Exchange, Inc.

[32] Section 6(b)(3) of the Act, 15 U.S.C. 78f(b)(3).

[33] *See, e.g.,* Securities Exchange Act Release Nos. 53128 (January 13, 2006), 71 FR 3550, 3553 (January 23, 2006) (File No. 10–131); 53382 (February 27, 2006), 71 FR 11251, 11259 (March 6, 2006) (File No. SR–NYSE–2005–77); and 58375 (August 18, 2008), 73 FR 49498, 49501 (August 21, 2008) (File No. 10–182).

[34] 15 U.S.C. 78s(b)(2).

[35] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–62317; File No. SR–CBOE–2010–038]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Order Approving Proposed Rule Change, as Modified by Amendment No. 1 Thereto, Related to the Hybrid Matching Algorithms

June 17, 2010.

On April 22, 2010, the Chicago Board Options Exchange, Incorporated ("CBOE" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") [1] and Rule 19b–4 thereunder,[2] a proposed rule change to revise its market turner and modified participation entitlement priority overlays. On May 6, 2010, CBOE filed Amendment No. 1 to the proposed rule change. The proposed rule change was published for comment in the **Federal Register** on May 18, 2010.[3] The Commission received no comment letters on the proposal. This order approves the proposed rule change, as modified by Amendment No. 1.

CBOE Rules 6.45A (Priority and Allocation of Equity Option Trades on the CBOE Hybrid System), and 6.45B (Priority and Allocation of Trades in Index Options and Options on ETFs on the CBOE Hybrid System) set forth, among other things, the manner in which incoming electronic orders in options are allocated on the Hybrid System. Each rule currently provides allocation algorithms the Exchange can utilize when executing incoming electronic orders, including the Ultimate Matching Algorithm ("UMA"), and price-time and pro-rata priority allocation algorithms. The price-time and pro-rata priority overlays currently include: public customer priority for public customer orders resting on the Hybrid System; participation entitlements for certain qualifying market-makers (the "original participation entitlement(s)"); a market turner priority for participants that are the first to improve CBOE's disseminated quote; and a modified participation entitlement overlay [4] in which the original participation entitlement would apply only if there are no public customer orders resting at the best price or a public customer was the first to rest interest at the best price. In addition, a small order participation entitlement overlay for Designated Primary Market-Makers ("DPMs") and Lead Market-Makers ("LMMs") can be applied to each of the three allocation algorithms (*i.e.,* price-time, pro-rata or UMA).[5] These overlays are all optional.

The proposed rule change would amend the Exchange's priority overlays. CBOE proposes to make the market turner overlay available for classes utilizing any of the priority methods offered by the Exchange. The Exchange also proposes to amend the application of the modified participation entitlement overlay. Under the proposal, a Market-Maker that is the subject of a participation entitlement would only receive an entitlement if the amount it is entitled to pursuant to the participation entitlement is greater than the amount the Market-Maker would otherwise receive pursuant to the algorithm. In all other cases, the participation entitlement and public customer priority would not be applied. This allocation would be subject to the following:

- The Market-Maker's entitlement share would be calculated based on any remaining balance after all public customer orders at the best price are satisfied. For options classes using the pro-rata method, the Exchange may determine on a class-by-class basis to calculate the Market-Maker's entitlement share using the UMA methodology or the pro-rata methodology. For options classes using the price-time method, the Market-Maker's entitlement share would be calculated using the price-time methodology only.[6]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 62083 (May 12, 2010), 75 FR 27850.

[4] Securities Exchange Act Release No. 60665 (September 14, 2009), 74 FR 48114 (September 21, 2009) (SR–CBOE–2009–052).

[5] If the small order priority overlay is in effect for an option class, then orders for five (5) contracts or fewer will be executed first by the DPM or LMM, as applicable, appointed to the option class. This participation entitlement is subject to certain conditions, including a condition that public customer priority must be in effect in priority sequence ahead of the participation entitlement. *See* Rules 6.45A(a)(iii) and 6.45B(a)(iii).

[6] This modified participation entitlement overlay would only be applicable to automatic executions and would not be applicable for executions of incoming electronic orders initiated from PAR or from electronic auctions. Instead, the original

Continued

• When calculating the amount the Market-Maker would otherwise receive pursuant to the operation of the algorithm, the participation entitlement and public customer priority overlays would not be considered. Instead the calculation would be based on a price-time or pro-rata basis, as applicable, and subject to any other applicable priority overlays, such as market turner priority.

In addition, the Exchange proposes that the modified participation entitlement overlay would be available to modify the application of the small order participation entitlement.

The Commission has carefully reviewed the proposed rule change and finds that it is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[7] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[8] which requires, among other things, that the rules of an exchange be designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers; as well as Section 6(b)(8) of the Act, which requires the rules of an exchange not to impose any burden on competition not necessary or in furtherance of the Act.[9]

The Commission believes that the proposed rule change amending the market turner and modified participation entitlement overlays is consistent with the Act. All public customer orders at the best price will continue to be satisfied before a participation entitlement will be applied. If an entitlement is not applied, then the incoming order will be allocated among all market participants using the underlying matching algorithm—price-time or pro-rata—both of which the Commission already has found consistent with the Act.[10] In addition, the Exchange's overlay determinations will be distributed via regulatory circular. For these reasons, the Commission believes that the proposed rule change is consistent with the Act.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[11] that the proposed rule change (SR–CBOE–2010–038), as modified by Amendment No. 1, be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Florence E. Harmon,

Deputy Secretary.

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participation entitlement parameters would be applied for PAR and electronic auctions. In pro-rata classes where the UMA method is selected to calculate the Market-Maker's modified participation entitlement share, executions of incoming electronic orders initiated from PAR and electronic auctions would be allocated using the UMA method. Therefore, in such classes, the Market-Maker's original participation entitlement share of a PAR or electronic auction execution would be calculated using the UMA method.

[7] In approving this proposed rule change, the Commission has considered the proposed Rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78f(b)(8).

[10] *See* Securities Exchange Act Release No. 51822 (June 10, 2005), 70 FR 35321 (June 17, 2005) (Adopting CBOE Rule 6.45B).

[11] 15 U.S.C. 78s(b)(2).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–62322; File No. SR–MSRB–2010–04]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Discontinuation of the MSRB Public Access Facility

June 17, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 14, 2010, the Municipal Securities Rulemaking Board ("MSRB"), filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the MSRB. The MSRB has filed the proposal pursuant to Section 19(b)(3)(A)(iii) of the Act,[3] and Rule 19b–4(f)(3) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The MSRB has filed with the Commission a proposed rule change relating to its public access facility and access to printed copies of certain documents made available by the MSRB to the public.

The text of the proposed rule change is available on the MSRB's Web site at *http://www.msrb.org/msrb1/sec.asp,* at the MSRB's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the MSRB included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The MSRB has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The proposed rule change would (a) terminate the public access facility created under the MSRB's Municipal Securities Information Library ("MSIL") system[5] and (b) revise a related Rule G–37 interpretive Question & Answer to delete a reference to the public access facility. The public access facility is physically located at the offices of the MSRB and makes official statements and advance refunding documents available to the public for viewing and photocopying. Over the years, the MSRB has undertaken to make other items available through the public access facility including, but not limited to, copies of Forms G–37, G–37x and G–38t, certain transaction data and comment letters received in connection with requests for comment. All current information that is accessible to the public through the public access facility is now readily accessible through the MSRB Web site or the EMMA Web site. Accordingly, the MSRB will discontinue the public access facility but will retain the ability to provide photocopies of the documents for members of the public without Internet access, upon written

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(3).

[5] The MSIL system, originally established by the MSRB in 1990 to collect official statements and advance refunding documents, was discontinued for purposes of accepting submissions of such documents upon the establishment by the MSRB of its Electronic Municipal Market Access (EMMA) System's Primary Market Disclosure Service. The MSIL system continues to operate in a limited capacity for internal MSRB purposes only.

request, for a copying charge at a rate equal to the then-current Commission copying charge under its schedule of fees for records services as published on the Commission Web site.

2. Statutory Basis

The MSRB believes that the proposed rule change is consistent with Section 15B(b)(2)(C) of the Act,[6] which provides that the MSRB's rules shall:

be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in municipal securities, to remove impediments to and perfect the mechanism of a free and open market in municipal securities, and, in general, to protect investors and the public interest.

The MSRB believes that the proposed rule change is consistent with the Act since broad public access to documents otherwise available through the public access facility will continue to be available through the MSRB Web site, the EMMA Web site, or upon written request from the MSRB.

B. Self-Regulatory Organization's Statement on Burden on Competition

The MSRB does not believe the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The documents that are available through the public access facility are readily available to the public on an equal and nondiscriminatory manner on the MSRB Web site, the EMMA Web site, or upon written request from the MSRB.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[7] and Rule 19b–4(f)(3) thereunder[8] because it is concerned solely with the operation and administration of the MSRB. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[9]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–MSRB–2010–04 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–MSRB–2010–04. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the MSRB. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MSRB–2010–04 and should be submitted on or before July 15, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–15268 Filed 6–23–10; 8:45 am]

BILLING CODE 8010–01–P

[6] 15 U.S.C. 78o–4(b)(2)(C).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(3).

[9] *See* Section 19(b)(3)(C) of the Act, 15 U.S.C. 78s(b)(3)(C).

[10] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 33 (Sub-No. 284X)]

Union Pacific Railroad Company—Abandonment Exemption—in Kane County, IL.

On June 4, 2010, Union Pacific Railroad Company (UP) filed with the Board a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to abandon a 3.17-mile line of railroad known as the St. Charles Industrial Lead, extending from milepost 35.13 to the end of the line at milepost 38.30, near St. Charles, in Kane County, Ill. The line traverses United States Postal Service Zip Code 60174, and includes no stations.

The line does not contain Federally granted rights-of-way. Any documentation in the possession of UP will be made available promptly to those requesting it.

The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, In Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued on or before September 22, 2010.

Any offer of financial assistance (OFA) under 49 CFR 1152.27(b)(2) will be due no later than 10 days after service of a decision granting the petition for exemption. Each OFA must be accompanied by a $1,500 filing fee. *See* 49 CFR 1002.2(f)(25).

All interested persons should be aware that, following abandonment of rail service and salvage of the line, the line may be suitable for other public use, including interim trail use. Any request for a public use condition under 49 CFR 1152.28 or for trail use/rail banking under 49 CFR 1152.29 will be due no later than July 14, 2010. Each

trail request must be accompanied by a $250 filing fee. *See* 49 CFR 1002.2(f)(27).

All filings in response to this notice must refer to Docket No. AB 33 (Sub-No. 284X), and must be sent to: (1) Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001; and (2) Mack H. Shumate, Jr., 101 North Wacker Drive, Room 1920, Chicago, Ill. 60606. Replies to the petition are due on or before July 14, 2010.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Assistance, Governmental Affairs and Compliance at (202) 245–0238 or refer to the full abandonment or discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Section of Environmental Analysis (SEA) at (202) 245–0305. Assistance for the hearing impaired is available through Federal Information Relay Service (FIRS) at 1–800–877–8339.

An environmental assessment (EA) (or environmental impact statement (EIS), if necessary) prepared by SEA will be served upon all parties of record and upon any agencies or other persons who commented during its presentation. Other interested persons may contact SEA to obtain a copy of the EA (or EIS). EAs in these abandonment proceedings normally will be made available within 60 days of the filing of the petition. The deadline for submission of comments on the EA generally will be within 30 days of its service.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: June 18, 2010.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2010–15290 Filed 6–23–10; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Reports, Forms and Record Keeping Requirements; Agency Information Collection Activity Under OMB Review

AGENCY: National Highway Traffic Safety Administration, DOT

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected burden. The **Federal Register** Notice with a 60-day comment period was published on July 20, 2009 (74 FR 35227).

DATES: Comments must be submitted on or before July 26, 2010.

FOR FURTHER INFORMATION CONTACT: Coleman Sachs, National Highway Traffic Safety Administration, Office of Vehicle Safety Compliance (NVS–223), 1200 New Jersey Avenue, SE., Room W43–481, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

National Highway Traffic Safety Administration

Title: 49 CFR part 566, Manufacturers' Identification.

OMB Number: 2127–0043.

Type of Request: Reinstatement of an information collection for which OMB approval has expired.

Affected Public: Business or other for-profit organizations.

Abstract: If a motor vehicle or item of replacement motor vehicle equipment contains a defect related to motor vehicle safety or fails to comply with an applicable Federal motor vehicle safety standard, the manufacturer is required under 49 U.S.C. 30118 to furnish notification of the defect or noncompliance to the Secretary of Transportation, as well as to owners, purchasers, and dealers of the motor vehicle or replacement equipment, and to remedy the defect or noncompliance without charge to the owner. To ensure that manufacturers are meeting these and other responsibilities under the statutes and regulations administered by NHTSA, the agency issued 49 CFR part 566, *Manufacturer Identification.* The regulations in part 566 require manufacturers of motor vehicles or motor vehicle equipment, other than tires, to which a Federal motor vehicle safety standard (FMVSS) applies, to submit to NHTSA, on a one-time basis, identifying information on themselves and on the products that they manufacture to those standards. The information must be submitted no later than 30 days after the manufacturer begins to manufacture motor vehicles or motor vehicle equipment subject to the FMVSS. No specific form need be used for the submission of this information. Manufacturers who have previously submitted identifying information must ensure that the information on file is accurate and complete by submitting revised information no later than 30 days after a change in the business that affects the validity of that information has occurred.

Estimated Burden Hours: 33.

Number of Respondents: 200.

ADDRESSES: Send comments, within 30 days, to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention NHTSA Desk Officer.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. A Comment to OMB is most effective if OMB receives it within 30 days of publication.

Issued on: June 17, 2010.

Claude Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2010–15292 Filed 6–23–10; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Action on Proposed Transportation Project in Illinois

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of limitation on claims for judicial review of actions by FHWA and other Federal agencies.

SUMMARY: This notice announces actions taken by the FHWA and other Federal agencies that are final within the meaning of 23 U.S.C. 139(*l*)(1). The actions relate to a proposed highway and transit project within the Tier 1 Elgin O'Hare—West Bypass study area, which is bounded roughly by I–90 on the north, I–294 on the east, I–290 on the south, and the Elgin O'Hare Expressway on the west and located in Cook and DuPage Counties in Illinois just northwest of the City of Chicago. The Federal actions, taken as a result of a tiered environmental review process under the National Environmental Policy Act, 42 U.S.C. 4321–4351 (NEPA), and implementing regulations

on tiering, 40 CFR 1502.20, 40 CFR 1508.28, and 23 CFR part 771, determined certain issues relating to the proposed project. Those Tier 1 decisions will be used by Federal agencies in subsequent proceedings, including decisions whether to grant licenses, permits, and approvals for the highway and transit project. Tier 1 decisions also may be relied upon by State and local agencies in proceedings on the proposed project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Tier 1 Federal agency actions of the proposed highway and transit project will be barred unless the claim is filed on or before December 21, 2010. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Mr. Norman R. Stoner, P.E., Division Administrator, Federal Highway Administration, 3250 Executive Park Drive, Springfield, Illinois 62703, Phone: (217) 492–4600, E-mail address: *Norman.Stoner@ dot.gov.* The FHWA Illinois Division Office's normal business hours are 7:30 a.m. to 4:15 p.m. You may also contact Ms. Diane M. O'Keefe, P.E., Illinois Department of Transportation, Deputy Director of Highways, Region One Engineer, 201 West Center Court, Schaumburg, Illinois 60196, Phone: (847) 705–4110. The Illinois Department of Transportation Region One's normal business hours are 8 a.m. to 4:30 p.m.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA has issued a Tier 1 Final Environmental Impact Statement (FEIS) and Record of Decision (ROD) in connection with proposed highway and transit projects within the Elgin O'Hare—West Bypass study area in Cook and DuPage Counties in Illinois. Decisions in the Tier 1 ROD include, but are not limited to, the following:

a. Purpose and need for the project, including improving regional and local travel by reducing congestion, improving travel efficiency, improving access to O'Hare Airport from the west, and improving modal opportunities and connections.

b. Alternative 203 with South Connection Option D will be carried forward for further evaluation in the Tier 2 environmental review process.

c. Alternatives have been eliminated from further consideration and study, including but not limited to, the No-Action Alternative, Alternative 402, and South Connection Option A.

Interested parties may consult the ROD and FEIS for further information on each of the decisions described above.

The Tier 1 actions by the Federal agencies, and the laws under which such actions were taken, are described in the FEIS for the project approved on April 30, 2010, the ROD approved June 17, 2010, and in other documents in the FHWA administrative record. The scope and purpose of the Tier 1 FEIS are described in Sections 1.1 and 1.2 of the FEIS. The FEIS, ROD and other documents in the FHWA administrative record are available by contacting FHWA or the Illinois Department of Transportation at the addresses provided above. Project information can be viewed and downloaded from the project Web site *http://www.elginohare-westbypass.org.* The FEIS can also be downloaded from *http://www.dot.il.gov/desenv/env.html,* or hard copies of the FEIS and the ROD are available upon request.

This notice applies to all Federal agency Tier 1 decisions that are final within the meaning of 23 U.S.C. 139(*l*)(1) as of the issuance date of this notice and all laws under which such actions were taken, including, but not limited to:

1. General: National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351] Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128].

2. Air: Clean Air Act [42 U.S.C. 7401–7671(q)].

3. Land: Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303 and 23 U.S.C. 138].

4. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq*].

5. Wetlands and Water Resources: Safe Drinking Water Act [42 U.S.C. 300(f)–300(j)(6)]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287].

6. Executive Orders: E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898 Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program).

Authority: 23 U.S.C. 139(l)(1)

Issued on: June 17, 2010.

Norman R. Stoner,

Division Administrator, Springfield, Illinois.

[FR Doc. 2010–15358 Filed 6–23–10; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in California; Notice of Statute of Limitations on Claims

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by the California Department of Transportation (Caltrans), pursuant to 23 USC 327, the US Army Corps of Engineers (USACOE), and the U.S. Fish and Wildlife Service (USFWS).

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans, USACOE, and USFWS, that are final within the meaning of 23 U.S.C. 139(*l*)(1). The actions relate to a proposed highway project, on Interstate 15 (I–15) between the existing Winchester Road (State Route 79, SR–79)/I–15 Interchange and Murrieta Hot Springs Road in the vicinity of the I–15/I–215 junction within the cities of Temecula and Murrieta in Riverside County, State of California. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before December 21, 2010. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For Caltrans: James Shankel, Senior Environmental Planner, Environmental Studies "C" Branch Chief, California Department of Transportation, District 8, Division of Environmental Planning, 464 West 4th Street, 6th Floor MS–827, San Bernardino, California 92401–1400, available 8 a.m.–5 p.m. Monday through Friday, phone number (909) 383–6379 or e-mail: *james_shankel@dot.ca.gov.* For USACOE: Stephanie J. Hall, Environmental Protection Specialist/Senior Project Manager, Regulatory Division, 915 Wilshire Blvd., Los

Angeles, CA 90017–3401, phone number (213) 452–3410. For USFWS: Sally Brown, 6010 Hidden Valley Road, Ste. 101, Carlsbad, CA 92011, phone number (760) 431–9440.

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the Federal Highway Administration (FHWA) assigned, and the California Department of Transportation (Caltrans) assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that Caltrans, USACOE, and USFWS have taken final agency actions subject to 23 U.S.C. 139(*l*)(1) by issuing licenses, permits, and approvals for the following highway project in the State of California: Construction of a new interchange, French Valley Parkway, along with enhancements to facilitate improved operations on the existing mainline facility. The purpose of the project is to improve traffic flow and enhance safety by reducing congestion. The project proposes a partial cloverleaf interchange at French Valley Parkway with loop on-ramps in the northwestern and southeastern quadrants and direct on-ramps in the southwestern and northeastern quadrants. French Valley Parkway will be constructed as a six-lane arterial highway from Jefferson Avenue to Ynez Road. Auxiliary lanes will be provided in both the northbound and southbound directions. An up to three-lane collector-distributor (C/D) system will be constructed parallel to I–15/I–215 confluence and Winchester Road in both the northbound and southbound directions. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Assessment (FEA) for the project, approved via issuance of a Finding of No Significant Impact (FONSI) on January 29, 2010, and in other documents in the FHWA project records. The FEA, FONSI, and other project records are available by contacting Caltrans at the addresses provided above.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal Aid-Highway Act of 1970 [23 U.S.C. 109].
2. *Air:* Clean Air Act, as amended [42 U.S.C. 7401–7671(q)].
3. *Wildlife:* Endangered Species Act [16 U.S.C. 1531–1544], Fish and Wildlife Coordination Act [16 U.S.C. 661–667 (d)], Migratory Bird Treaty Act [16 U.S.C. 703–712].
4. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470]; Antiquities Act of 1906 [16 U.S.C. 431–433].
5. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended [42 U.S.C. 61].
6. *Wetlands and Water Resources:* Clean Water Act, [33 U.S.C. 1251–1377].
7. *Hazardous Materials:* Comprehensive Environmental Response, Compensation, and Liability Act [42 U.S.C. 9601–9675]; Resource Conservation and Recovery Act [42 U.S.C. 6901–6992(j)].
8. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898 Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; and E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1)

Issued on: June 18, 2010.

Karen A. Bobo,

Director, Local Programs, Federal Highway Administration, Sacramento, California.

[FR Doc. 2010–15291 Filed 6–23–10; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

Savings Association Holding Company Report H–(b)11

AGENCY: Office of Thrift Supervision (OTS), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The proposed information collection request (ICR) described below has been submitted to the Office of Management and Budget (OMB) for review and approval, as required by the Paperwork Reduction Act of 1995. OTS is soliciting public comments on the proposal.

DATES: Submit written comments on or before July 26, 2010. A copy of this ICR, with applicable supporting documentation, can be obtained from RegInfo.gov at *http://www.reginfo.gov/public/do/PRAMain.*

FOR FURTHER INFORMATION CONTACT: For further information or to obtain a copy of the submission to OMB, please contact Ira L. Mills at, *ira.mills@ots.treas.gov* (202) 906–6531, or facsimile number (202) 906–6518, Regulations and Legislation Division, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: OTS may not conduct or sponsor an information collection, and respondents are not required to respond to an information collection, unless the information collection displays a currently valid OMB control number. As part of the approval process, we invite comments on the following information collection.

Title of Proposal: Savings Association Holding Company Report H–(b)11

OMB Number: 1550–0060.

Form Number: OTS Form H–(b)11.

Regulation requirement: 12 CFR 584.1.

Description: Section 10(b) of the Home Owners' Loan Act and 12 CFR 584.1(a)(2) provide that each savings and loan holding company is required to file an annual report H–(b)11 within 90 days of the end of its fiscal year. Quarterly filings are also required within 45 days of the end of the first three fiscal quarters, and should describe any material changes from the most recently filed H–(b)11. If material changes have occurred during the fourth quarter, an H–(b)11 filing must be filed within 45 days of the end of the holding company's fiscal fourth quarter as well. The information gathered is essential for OTS to monitor whether savings and loan holding companies are in compliance with applicable statutes, regulations, and conditions of approval to acquire an insured savings association.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 951.

Estimated Burden Hours per Response: 2 hours.

Estimated Frequency of Response: On occasion; quarterly; other.

Estimated Total Burden: 7,608 hours.

Clearance Officer: Ira L. Mills, (202) 906–6531, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

Dated: June 21, 2010.

Ira L. Mills,

Paperwork Clearance Officer, Office of Chief Counsel, Office of Thrift Supervision.

[FR Doc. 2010–15343 Filed 6–23–10; 8:45 am]

BILLING CODE 6720–01–P

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable On Federal Bonds—Change in Business Address and Redomestication: First Liberty Insurance Corporation; Liberty Insurance Corporation; LM Insurance Corporation

AGENCY: Financial Management Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 13 to the Treasury Department Circular 570, 2009 Revision, published July 1, 2009, at 74 FR 31536.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874–6850.

SUPPLEMENTARY INFORMATION: Notice is hereby given by the Treasury that the above-named companies formally changed their "BUSINESS ADDRESS" to "2815 Forbs Avenue, Suite 200, Hoffman Estates, IL 60192" effective immediately. In addition, The First Liberty Insurance Corporation (NAIC# 33588) and LM Insurance Corporation (NAIC# 33600) have redomesticated from the state of Iowa to the state of Illinois effective September 2, 2009. Federal bond-approving officers should annotate their reference copies of the Treasury Circular 570 ("Circular"), 2009 Revision, to reflect these changes.

The Circular may be viewed and downloaded through the Internet at *http://www.fms.treas.gov/c570.*

Questions concerning this Notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F01, Hyattsville, MD 20782.

Dated: June 10, 2010.

William J. Erie,

Acting Director, Financial Accounting and Services Division.

[FR Doc. 2010–15064 Filed 6–23–10; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable On Federal Bonds—Change In Business Address: American Economy Insurance Company; American Fire and Casualty Company; American States Insurance Company; Employers Insurance Company of Wausau; Liberty Mutual Fire Insurance Company; Ohio Casualty Insurance Company; Peerless Insurance Company; West American Insurance Company

AGENCY: Financial Management Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 15 to the Treasury Department Circular 570, 2009 Revision, published July 1, 2009, at 74 FR 31536.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874–6850.

SUPPLEMENTARY INFORMATION: Notice is hereby given by the Treasury that the above-named companies formally changed their "BUSINESS ADDRESS" as follows:

American Economy Insurance Company (NAIC #19690). BUSINESS ADDRESS: 500 North Meridian Street, Indianapolis, IN 46204.

American Fire and Casualty Company (NAIC #24066). BUSINESS ADDRESS: 9450 Seward Road, Fairfield, OH 45014.

American States Insurance Company (NAIC #19704). BUSINESS ADDRESS: 500 North Meridian Street, Indianapolis, IN 46204.

Employers Insurance Company of Wausau (NAIC #21458) BUSINESS ADDRESS: 2000 Westwood Drive, Wausau, WI 54401.

Liberty Mutual Fire Insurance Company (NAIC #23035). BUSINESS ADDRESS: 2000 Westwood Drive, Wausau, WI 54401.

Ohio Casualty Insurance Company (The) (NAIC #24074). BUSINESS ADDRESS: 9450 Seward Road, Fairfield, OH 45014.

Peerless Insurance Company (NAIC #24198). BUSINESS ADDRESS: 62 Maple Avenue, Keene, NH 03431.

West American Insurance Company (NAIC #44393). BUSINESS ADDRESS: 7999 Knue Road, Suite 450, Indianapolis, IN 46250–1901.

Federal bond-approving officers should annotate their reference copies of the Treasury Circular 570 ("Circular"), 2009 Revision, to reflect these changes.

The Circular may be viewed and downloaded through the Internet at *http://www.fms.treas.gov/c570.*

Questions concerning this Notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F01, Hyattsville, MD 20782.

Dated: June 10, 2010.

William J. Erie,

Acting Director, Financial Accounting and Services Division.

[FR Doc. 2010–15065 Filed 6–23–10; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds—Terminations: Victore Insurance Company

AGENCY: Financial Management Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 17 to the Treasury Department Circular 570, 2009 Revision, published July 1, 2009, at 74 FR 31536.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874–6850.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Certificate of Authority issued by the Treasury to the above-named company under 31 U.S.C. 9305 to qualify as acceptable surety on Federal bonds is terminated effective today. Federal bond-approving officials should annotate their reference copies of the Treasury Department Circular 570 ("Circular"), 2009 Revision, to reflect this change.

With respect to any bonds currently in force with this company, bond-approving officers may let such bonds run to expiration and need not secure new bonds. However, no new bonds should be accepted from this company, and bonds that are continuous in nature should not be renewed.

The Circular may be viewed and downloaded through the Internet at *http://www.fms.treas.gov/c570.*

Questions concerning this notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F01, Hyattsville, MD 20782.

Dated: June 10, 2010.

William J. Erie,

Acting Director, Financial Accounting and Services Division.

[FR Doc. 2010–15066 Filed 6–23–10; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0046]

Proposed Information Collection (Statement of Heirs for Payment of Credits Due Estate of Deceased Veteran) Activity: Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to determine a claimant's eligibility for refundable credit.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before August 23, 2010.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *http://www.Regulations.gov;* or to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail *nancy.kessinger@va.gov.* Please refer to "OMB Control No. 2900–0046" in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 461–9769 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Statement of Heirs for Payment of Credits Due Estate of Deceased Veteran, VA Form Letter 29–596.

OMB Control Number: 2900–0046.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 29–596 is use by administrator, executor, or next of kin to support a claim for money in the form of unearned or unapplied insurance premiums due to a deceased veteran's estate.

Affected Public: Individuals or households.

Estimated Annual Burden: 78 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 312.

Dated: June 18, 2010.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2010–15263 Filed 6–23–10; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0066]

Proposed Information Collection (Request to Employer for Employment Information in Connection With Claim for Disability Benefits) Activity: Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to determine a claimant's eligibility for disability insurance benefits.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before August 23, 2010.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *http://www.Regulations.gov;* or to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail *nancy.kessinger@va.gov.* Please refer to "OMB Control No. 2900–0066" in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 461–9769 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Request to Employer for Employment Information in Connection With Claim for Disability Benefits, VA Form Letter 29–459.

OMB Control Number: 2900–0066.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form Letter 29–459 is used to request employment information from an employer in connection with a claim for disability benefits. VA uses the information to establish the insured's eligibility for disability insurance benefits.

Affected Public: Individuals or households.

Estimated Annual Burden: 862 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 5,167.

Dated: June 18, 2010.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2010–15264 Filed 6–23–10; 8:45 am]

BILLING CODE 8320–01–P

Federal Register

Thursday,
June 24, 2010

Part II

Department of Health and Human Services

45 CFR Part 170

Establishment of the Temporary Certification Program for Health Information Technology; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 170

RIN 0991–AB59

Establishment of the Temporary Certification Program for Health Information Technology

AGENCY: Office of the National Coordinator for Health Information Technology, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This final rule establishes a temporary certification program for the purposes of testing and certifying health information technology. This final rule is established under the authority granted to the National Coordinator for Health Information Technology (the National Coordinator) by section 3001(c)(5) of the Public Health Service Act (PHSA), as added by the Health Information Technology for Economic and Clinical Health (HITECH) Act. The National Coordinator will utilize the temporary certification program to authorize organizations to test and certify Complete Electronic Health Records (EHRs) and/or EHR Modules, thereby making Certified EHR Technology available prior to the date on which health care providers seeking incentive payments available under the Medicare and Medicaid EHR Incentive Programs may begin demonstrating meaningful use of Certified EHR Technology.

DATES: These regulations are effective June 24, 2010. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of June 24, 2010.

FOR FURTHER INFORMATION CONTACT: Steven Posnack, Director, Federal Policy Division, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology, 202–690–7151.

SUPPLEMENTARY INFORMATION:

Acronyms

APA Administrative Procedure Act
ARRA American Recovery and Reinvestment Act of 2009
CAH Critical Access Hospital
CCHIT Certification Commission for Health Information Technology
CGD Certification Guidance Document
CHPL Certified Health Information Technology Products List
CMS Centers for Medicare & Medicaid Services
CORE Committee on Operating Rules for Information Exchange®
EHR Electronic Health Record
FACA Federal Advisory Committee Act
FFP Federal Financial Participation
FFS Fee for Service (Medicare Program)
HHS Department of Health and Human Services
HIPAA Health Insurance Portability and Accountability Act
HIT Health Information Technology
HITECH Health Information Technology for Economic and Clinical Health
ISO International Organization for Standardization
IT Information Technology
MA Medicare Advantage
NHIN Nationwide Health Information Network
NIST National Institute of Standards and Technology
OIG Office of Inspector General
OMB Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
ONC–ACB ONC–Authorized Certification Body
ONC–ATCB ONC–Authorized Testing and Certification Body
OPM Office of Personnel Management
PHSA Public Health Service Act
RFA Regulatory Flexibility Act
RIA Regulatory Impact Analysis
SDO Standards Development Organization
SSA Social Security Act

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I. Background

A. Previously Defined Terminology

In addition to new terms and definitions created by this rule, the following terms have the same meaning as provided at 45 CFR 170.102.

- *Certification criteria*
- *Certified EHR Technology*
- *Complete EHR*
- *Disclosure*
- *EHR Module*
- *Implementation specification*
- *Qualified EHR*
- *Standard*

B. Legislative and Regulatory History

1. Legislative History

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created "Title XXX—Health Information Technology and Quality" (Title XXX) to improve health care quality, safety, and efficiency through the promotion of health information technology (HIT) and electronic health information exchange. Section 3001 of the PHSA establishes the Office of the National Coordinator for Health Information Technology (ONC). Title XXX of the PHSA provides the National Coordinator for Health Information Technology (the National Coordinator) and the Secretary of Health and Human Services (the Secretary) with new responsibilities and authorities related to HIT. The HITECH Act also amended several sections of the Social Security Act (SSA) and in doing so established the availability of incentive payments to eligible professionals and eligible hospitals to promote the adoption and meaningful use of interoperable HIT.

a. Standards, Implementation Specifications, and Certification Criteria

With the passage of the HITECH Act, two new Federal advisory committees were established, the HIT Policy Committee and the HIT Standards Committee (sections 3002 and 3003 of the PHSA, respectively). Each is responsible for advising the National Coordinator on different aspects of standards, implementation specifications, and certification criteria. The HIT Policy Committee is responsible for, among other duties, recommending priorities for the development, harmonization, and recognition of standards, implementation specifications, and certification criteria, while the HIT Standards Committee is responsible for recommending standards, implementation specifications, and certification criteria for adoption by the Secretary under section 3004 of the PHSA consistent with the ONC-coordinated Federal Health IT Strategic Plan (the "strategic plan").

Section 3004 of the PHSA defines how the Secretary adopts standards, implementation specifications, and certification criteria. Section 3004(a) of the PHSA defines a process whereby an obligation is imposed on the Secretary to review standards, implementation specifications, and certification criteria and identifies the procedures for the Secretary to follow to determine whether to adopt any group of standards, implementation specifications, or certification criteria included among National Coordinator-endorsed recommendations.

b. Medicare and Medicaid EHR Incentive Programs

Title IV, Division B of the HITECH Act establishes incentive payments under the Medicare and Medicaid programs for eligible professionals and eligible hospitals that meaningfully use Certified Electronic Health Record (EHR) Technology. The Centers for Medicare & Medicaid Services (CMS) is charged with developing the Medicare and Medicaid EHR incentive programs.

i. Medicare EHR Incentive Program

Section 4101 of the HITECH Act added new subsections to section 1848 of the SSA to establish incentive payments for the meaningful use of Certified EHR Technology by eligible professionals participating in the Medicare Fee-for-Service (FFS) program beginning in calendar year (CY) 2011 and beginning in CY 2015, downward payment adjustments for covered professional services provided by eligible professionals who are not meaningful users of Certified EHR Technology. Section 4101(c) of the HITECH Act added a new subsection to section 1853 of the SSA that provides incentive payments to Medicare Advantage (MA) organizations for their affiliated eligible professionals who meaningfully use Certified EHR Technology beginning in CY 2011 and beginning in CY 2015, downward payment adjustments to MA organizations to account for certain affiliated eligible professionals who are not meaningful users of Certified EHR Technology.

Section 4102 of the HITECH Act added new subsections to section 1886 of the SSA that establish incentive payments for the meaningful use of Certified EHR Technology by subsection (d) hospitals (defined under section 1886(d)(1)(B) of the SSA) that participate in the Medicare FFS program beginning in Federal fiscal year (FY) 2011 and beginning in FY 2015, downward payment adjustments to the market basket updates for inpatient hospital services provided by such hospitals that are not meaningful users of Certified EHR Technology. Section 4102(b) of the HITECH Act amends section 1814 of the SSA to provide an incentive payment to critical access hospitals that meaningfully use Certified EHR Technology based on the hospitals' reasonable costs beginning in FY 2011 and downward payment adjustments for inpatient hospital services provided by such hospitals that are not meaningful users of Certified EHR Technology for cost reporting periods beginning in FY 2015. Section 4102(c) of the HITECH Act adds a new subsection to section 1853 of the SSA to provide incentive payments to MA organizations for certain affiliated eligible hospitals that meaningfully use Certified EHR Technology and beginning in FY 2015, downward payment adjustments to MA organizations for those affiliated hospitals that are not meaningful users of Certified EHR Technology.

ii. Medicaid EHR Incentive Program

Section 4201 of the HITECH Act amends section 1903 of the SSA to provide 100 percent Federal financial participation (FFP) to States for incentive payments to eligible health care providers participating in the Medicaid program and 90 percent FFP for State administrative expenses related to the incentive program.

c. HIT Certification Programs

Section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of HIT. Specifically, section 3001(c)(5)(A) specifies that the "National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle" (*i.e.,* certification criteria adopted by the Secretary under section 3004 of the PHSA). The certification program(s) must also "include, as appropriate, testing of the technology in accordance with section 13201(b) of the [HITECH] Act."

Section 13201(b) of the HITECH Act requires that with respect to the development of standards and implementation specifications, the Director of the National Institute of Standards and Technology (NIST), in coordination with the HIT Standards Committee, "shall support the establishment of a conformance testing infrastructure, including the development of technical test beds." The United States Congress also indicated that "[t]he development of this conformance testing infrastructure may include a program to accredit independent, non-Federal laboratories to perform testing."

2. Regulatory History and Related Guidance

a. Initial Set of Standards, Implementation Specifications, and Certification Criteria Interim Final Rule

In accordance with section 3004(b)(1) of the PHSA, the Secretary issued an interim final rule with request for comments entitled "Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology" (HIT Standards and Certification Criteria interim final rule) (75 FR 2014), which adopted an initial set of standards, implementation specifications, and certification criteria. The standards, implementation specifications, and certification criteria adopted by the Secretary establish the capabilities that Certified EHR Technology must include in order to, at a minimum, support the achievement of what has been proposed for meaningful use Stage 1 by eligible professionals and eligible hospitals under the Medicare and Medicaid EHR Incentive Programs proposed rule (see 75 FR 1844 for more information about meaningful use and the proposed Stage 1 requirements).

b. Medicare and Medicaid EHR Incentive Programs Proposed Rule

On January 13, 2010, CMS published in the **Federal Register** (75 FR 1844) the Medicare and Medicaid EHR Incentive Programs proposed rule. The rule proposes a definition for meaningful use Stage 1 and regulations associated with the incentive payments made available under Division B, Title IV of the HITECH Act. CMS has proposed that meaningful use Stage 1 would begin in 2011 and has proposed that Stage 1 would focus on "electronically capturing health information in a coded format; using that information to track key clinical conditions and communicating that information for care coordination purposes (whether that information is structured or unstructured), but in structured format whenever feasible; consistent with other provisions of Medicare and Medicaid law, implementing clinical decision support tools to facilitate disease and medication management; and reporting clinical quality measures and public health information."

c. HIT Certification Programs Proposed Rule and the Temporary Certification Program Final Rule

Section 3001(c)(5) of the PHSA, specifies that the National Coordinator "shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted [by the Secretary] under this subtitle." Based on this authority, we proposed both a temporary and permanent certification program for HIT in a notice of proposed rulemaking entitled "Proposed Establishment of Certification Programs for Health Information Technology" (75 FR 11328, March 10, 2010) (RIN 0991–AB59) (the "Proposed Rule"). In the Proposed Rule, we proposed to use the certification programs for the purposes of testing and certifying HIT. We also specified the processes the National Coordinator would follow to authorize organizations to perform the certification of HIT.

We stated in the Proposed Rule that we expected to issue separate final rules for each of the certification programs. This final rule establishes a temporary certification program whereby the National Coordinator will authorize organizations to test and certify Complete EHRs and/or EHR Modules, thereby assuring the availability of Certified EHR Technology prior to the date on which health care providers seeking the incentive payments available under the Medicare and Medicaid EHR Incentive Programs may begin demonstrating meaningful use of Certified EHR Technology.

d. Recognized Certification Bodies as Related to the Physician Self-Referral Prohibition and Anti-Kickback EHR Exception and Safe Harbor Final Rules

In August 2006, HHS published two final rules in which CMS and the Office of Inspector General (OIG) promulgated an exception to the physician self-referral prohibition and a safe harbor under the anti-kickback statute, respectively, for certain arrangements involving the donation of interoperable EHR software to physicians and other health care practitioners or entities (71 FR 45140 and 71 FR 45110, respectively). The exception and safe harbor provide that EHR software will be "deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the [physician/recipient]." ONC published separately a Certification Guidance Document (CGD) (71 FR 44296) to explain the factors ONC would use to determine whether to recommend to the Secretary a body for "recognized certification body" status. The CGD serves as a guide for ONC to evaluate applications for "recognized certification body" status and provides the information a body would need to apply for and obtain such status. To date, the Certification Commission for Health Information Technology (CCHIT) has been the only organization that has both applied for and been granted "recognized certification body" status under the CGD.

In section VI of the CGD, ONC notified the public, including potential applicants, that the recognition process explained in the CGD would be formalized through notice and comment rulemaking and that when a final rule has been promulgated to govern the process by which a "recognized certification body" is determined, certification bodies recognized under the CGD would be required to complete

new applications and successfully demonstrate compliance with all requirements of the final rule.

In the Proposed Rule, we began the formal notice and comment rulemaking described in the CGD. We stated that the processes we proposed for the temporary certification program and permanent certification program, once finalized, would supersede the CGD, and the authorization process would constitute the new established method for "recognizing" certification bodies, as referenced in the physician self-referral prohibition and anti-kickback EHR exception and safe harbor final rules. As a result of our proposal, certifications issued by a certification body "authorized" by the National Coordinator would constitute certification by "a certifying body recognized by the Secretary" in the context of the physician self-referral EHR exception and anti-kickback EHR safe harbor. We requested public comment on this proposal and have responded to those comments in Section III of this final rule.

II. Overview of the Temporary Certification Program

The temporary certification program provides a process by which an organization or organizations may become an ONC–Authorized Testing and Certification Body (ONC–ATCB) and be authorized by the National Coordinator to perform the testing and certification of Complete EHRs and/or EHR Modules.

Under the temporary certification program, the National Coordinator will accept applications for ONC–ATCB status at any time. In order to become an ONC–ATCB, an organization or organizations must submit an application to the National Coordinator to demonstrate its competency and ability to test and certify Complete EHRs and/or EHR Modules. An applicant will need to be able to both test and certify Complete EHRs and/or EHR Modules. We anticipate that only a few organizations will qualify and become ONC–ATCBs under the temporary certification program. These organizations will be required to remain in good standing by adhering to the Principles of Proper Conduct for ONC–ATCBs. ONC–ATCBs will also be required to follow the conditions and requirements applicable to the testing and certification of Complete EHRs and/or EHR Modules as specified in this final rule. The temporary certification program will sunset on December 31, 2011, or if the permanent certification program is not fully constituted at that time, then upon a subsequent date that is determined to be appropriate by the National Coordinator.

III. Provisions of the Temporary Certification Program; Analysis and Response to Public Comments on the Proposed Rule

A. Overview

This section discusses the 84 timely received comments on the Proposed Rule's proposed temporary certification program and our responses. We have structured this section of the final rule based on the proposed regulatory sections of the temporary certification program and discuss each regulatory section sequentially. For each discussion of the regulatory provision, we first restate or paraphrase the provision as proposed in the Proposed Rule as well as identify any correlated issues for which we sought public comment. Second, we summarize the comments received. Lastly, we provide our response to the comments, including stating whether we will finalize the provision as proposed in the Proposed Rule or modify the proposed provision in response to public comment. Comments on the incorporation of the "recognized certification body" process, "grandfathering" of certifications, the concept of "self-developed," validity and expiration of certifications, general comments, and comments beyond the scope of this final rule are discussed towards the end of the preamble.

B. Scope and Applicability

In the Proposed Rule, we indicated in section 170.400 that the temporary certification program would serve to implement section 3001(c)(5) of the Public Health Service Act, and that subpart D would also set forth the rules and procedures related to the temporary certification program for HIT administered by the National Coordinator. Under section 170.401, we proposed that subpart D would establish the processes that applicants for ONC–ATCB status must follow to be granted ONC–ATCB status by the National Coordinator, the processes the National Coordinator would follow when assessing applicants and granting ONC–ATCB status, and the requirements of ONC–ATCBs for testing and certifying Complete EHRs and/or EHR Modules in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part.

Comments. We received many comments that expressed support for our proposal for a temporary certification program that would provide the opportunity for Complete EHRs and EHR Modules to be tested and certified in advance of meaningful use Stage 1. The commenters expressed an understanding of the rationale we provided for proposing a temporary certification program and the urgency we associated with establishing the temporary certification program.

Some commenters suggested that we use the terms "interim," "transitional" or "provisional" to describe the temporary certification program. One commenter asserted that the term "interim" is particularly appropriate because it is used in Federal rulemaking to denote regulatory actions that are fully in effect but will be replaced with more refined versions in the future. Other commenters contended that using the term "temporary" to describe the short-term program and its associated certifications may cause confusion in the market and prolong, instead of reduce, uncertainty among eligible professionals and eligible hospitals. One commenter recommended that we establish a comprehensive educational program about our proposed certification programs.

Some commenters stated that the certification programs should not be vague and expansive by encompassing various, unidentified areas of HIT, but instead should be targeted to the objectives of achieving meaningful use of Certified EHR Technology. One commenter also mentioned the need for the certification programs to focus on the implementation of the Nationwide Health Information Network (NHIN).

Response. We appreciate the commenters' expressions of support for the temporary certification program. We also appreciate the commenters' suggestions and rationale for renaming the temporary certification program. We believe, however, that we have described the temporary certification program in the Proposed Rule and this final rule in a manner that clearly conveys its purpose and scope such that renaming the program is not necessary. Furthermore, as generally recommended by a commenter, we will continue to communicate with and educate stakeholders about the temporary certification program and the eventual transition to the proposed permanent certification program.

We believe that we clearly indicated in the Proposed Rule's preamble and the proposed temporary certification program's scope and applicability provisions that one of the goals of the temporary certification program is to support the achievement of meaningful use by testing and certifying Complete EHRs and EHR Modules to the certification criteria adopted by the

Secretary in subpart C of part 170. Therefore, we do not believe that the programs are overly vague or expansive. We believe that the commenters who expressed these concerns focused on our proposals to permit other types of HIT to be certified under the permanent certification program. We plan to address this issue in the final rule for the permanent certification program, but in the interim, we remind these commenters of a fact we stated in the Proposed Rule. The Secretary would first need to adopt certification criteria for other types of HIT before we would consider authorizing, in this case, ONC–ACBs to certify those other types of HIT.

We are revising § 170.401 to clearly state that this subpart includes requirements that ONC–ATCBs must follow to maintain good standing under the temporary certification program. This reference was inadvertently left out of § 170.401 in the Proposed Rule.

C. Definitions and Correspondence

We proposed in the Proposed Rule to define three terms related to the temporary certification program and to establish a process for applicants for ONC–ATCB status and ONC–ATCBs to correspond with the National Coordinator.

1. Definitions

a. Days

We proposed in the Proposed Rule to add the definition of "day or days" to section 170.102. We proposed to define "day or days" to mean a calendar day or calendar days. We did not receive any comments on this provision. Therefore, we are finalizing this definition without modification.

b. Applicant

We proposed in section 170.402 to define applicant to mean a single organization or a consortium of organizations that seeks to become an ONC–ATCB by requesting and subsequently submitting an application for ONC–ATCB status to the National Coordinator.

Comments. One commenter recommended that we encourage and support the establishment of coalitions or partnerships for testing and certification that leverage specialized expertise. Another commenter asked whether third-party organizations will be allowed to become testing laboratories for the temporary and permanent certification programs.

Response. We agree with the commenter that coalitions or partnerships for testing and certification are capable of leveraging specialized expertise and we continue to support such an approach. We noted in the Proposed Rule that single organizations and consortia would be eligible to apply for ONC–ATCB status under the temporary certification program. We also stated that we would expect a consortium to be comprised of one organization that would serve as a testing laboratory and a separate organization that would serve as a certification body. We further stated that, as long as such an applicant could perform all of the required responsibilities of an ONC–ATCB, we would fully support the approach. Accordingly, we are finalizing this provision without modification.

Although we are unclear as to what the commenter meant by a "third-party organization," we can state that a testing laboratory could apply to become an ONC–ATCB in a manner described above (*i.e.,* as a member or component of a consortium) or the laboratory could apply independently to become an ONC–ATCB, but it would need to meet all the application requirements, including the requisite certification body qualifications as specified in ISO/IEC Guide 65:1996 (Guide 65). In the Proposed Rule, we proposed that a testing laboratory would need to become accredited by the testing laboratory accreditor under the permanent certification program. This process and whether an organization that becomes an ONC–ACB under the permanent certification program can be affiliated with an accredited testing laboratory are matters we requested the public to comment on in the Proposed Rule and will be more fully discussed when we finalize the permanent certification program.

c. ONC–ATCB

We proposed in section 170.402 to define an ONC–Authorized Testing and Certification Body (ONC–ATCB) to mean an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to subpart D to perform the testing and certification of Complete EHRs and/or EHR Modules under the temporary certification program. We did not receive any comments on this provision. Therefore, we are finalizing this definition without modification.

2. Correspondence

We proposed in section 170.405 to require applicants for ONC–ATCB status and ONC–ATCBs to correspond and communicate with the National Coordinator by e-mail, unless otherwise necessary. We proposed that the official date of receipt of any e-mail between the National Coordinator and an applicant for ONC–ATCB status or an ONC–ATCB would be the day the e-mail was sent. We further proposed that in circumstances where it was necessary for an applicant for ONC–ATCB status or ONC–ATCB to correspond or communicate with the National Coordinator by regular or express mail, the official date of receipt would be the date of the delivery confirmation. We did not receive any comments on these proposals. We are, however, revising this section to include "or ONC–ATCB" in paragraph (b) to clarify that either an applicant for ONC–ATCB status or an ONC–ATCB may, when necessary, utilize the specified correspondence methods. This reference was inadvertently left out of § 170.405(b) in the Proposed Rule.

D. Testing and Certification

1. Distinction Between Testing and Certification

We stated in the Proposed Rule that there is a distinct difference between the "testing" and "certification" of a Complete EHR and/or EHR Module. We described "testing" as the process used to determine the degree to which a Complete EHR or EHR Module can meet specific, predefined, measurable, and quantitative requirements. We noted that such results would be able to be compared to and evaluated in accordance with predefined measures. In contrast, we described "certification" as the assessment (and subsequent assertion) made by an organization, once it has analyzed the quantitative results rendered from testing along with other qualitative factors, that a Complete EHR or EHR Module has met all of the applicable certification criteria adopted by the Secretary. We noted that qualitative factors could include whether a Complete EHR or EHR Module developer has a quality management system in place, or whether the Complete EHR or EHR Module developer has agreed to the policies and conditions associated with being certified (*e.g.,* proper logo usage). We further stated that the act of certification typically promotes confidence in the quality of a product (and the Complete EHR or EHR Module developer that produced it), offers assurance that the product will perform as described, and helps consumers to differentiate which products have met specific criteria from others that have not.

To further clarify, we stated that a fundamental difference between testing and certification is that testing is intended to result in objective,

unanalyzed data. In contrast, certification is expected to result in an overall assessment of the test results, consideration of their significance, and consideration of other factors to determine whether the prerequisites for certification have been achieved. To illustrate an important difference between testing and certification, we provided the example that we recite below.

An e-prescribing EHR Module developer that seeks to have its EHR Module certified would first submit the EHR Module to be tested. To successfully pass the established testing requirements, the e-prescribing EHR Module would, among other functions, need to transmit an electronic prescription using mock patient data according to the standards adopted by the Secretary. Provided that the e-prescribing EHR Module successfully passed this test it would next be evaluated for certification. Certification could require that the EHR Module developer agree to a number of provisions, including, for example, displaying the EHR Module's version and revision number so potential purchasers could discern when the EHR Module was last updated or certified. If the EHR Module developer agreed to all of the applicable certification requirements and the EHR Module achieved a passing test result, the e-prescribing EHR Module would be certified. In these situations, both the EHR Module passing the technical requirements tests and the EHR Module vendor meeting the other certification requirements would be required for the EHR Module to achieve certification.

Comments. Multiple commenters asked for additional clarification for the distinction between testing and certification. Commenters were concerned that ONC–ATCBs would have too much discretion related to certification. The commenters asserted that ONC–ATCBs should only be empowered to assess whether adopted certification criteria have been met or whether other applicable policies adopted by the National Coordinator through regulation, such as "labeling" policies, have been complied with. Commenters expressed specific concern with one of our examples of potential qualitative factors, which was the need to have "a quality management system in place." The commenters suggested that a requirement to have a quality management system in place is vague and gave too much discretion to an ONC–ATCB.

Response. We require as a Principle of Proper Conduct that ONC–ATCBs shall operate their certification programs in accordance with Guide 65. Guide 65 specifies the requirements that an organization must follow to operate a certification program. Moreover, because Guide 65 states in section 4.6.1 that a "certification body shall specify the conditions for granting, maintaining and extending certification," we believe that it would be inappropriate to dictate every specific aspect related to an ONC–ATCB's certification program operations. We understand the concerns expressed by commenters over our example of a "quality management system" as another factor that ONC–ATCBs may choose to include, in accordance with Guide 65, as part of their certification requirements for assessing Complete EHRs and/or EHR Modules and have considered how to best address such concerns.

With respect to those commenters who requested that we clarify the purview of ONC–ATCBs related to certification and expressed concerns about the discretion afforded to ONC–ATCBs, we agree that additional clarity is necessary regarding our intent and expectations of ONC–ATCBs in our discussion of the differences between testing and certification in the Proposed Rule. We believe commenters were expressing a concern that certification could include other factors beyond the certification criteria adopted by the Secretary in subpart C of part 170, which could prevent them from receiving a certification in a timely manner if they were not aware of those factors. We agree with commenters that this is a legitimate concern and did not intend to convey, through our examples, that we would adopt additional requirements for certification in this final rule beyond the certification criteria adopted by the Secretary in subpart C of part 170 and the other responsibilities specified in subpart D of part 170 that we require an ONC–ATCB to fulfill in order to perform the testing and certification of Complete EHRs and/or EHR Modules.

We seek to make clear that the primary responsibility of ONC–ATCBs under the temporary certification program is to test and certify Complete EHRs and/or EHR Modules in accordance with the certification criteria adopted by the Secretary. In consideration of the comments and the preceding discussion, we have revised § 170.445 and § 170.450 to make it explicitly clear that an ONC–ATCB must offer the option of testing and certification of a Complete EHR or EHR Module solely to the certification criteria adopted by the Secretary and no other certification criteria. In other words, an ONC–ATCB must comply with a request made by a Complete EHR or EHR Module developer to have its Complete EHR or EHR Module tested and certified solely to the certification criteria adopted by the Secretary and not to any other factors beyond those we require ONC–ATCBs to follow when issuing a certification as discussed above (*i.e.,* responsibilities specified in subpart D of part 170). However, this does not preclude an ONC–ATCB from also offering testing and certification options that include additional requirements beyond the certification criteria adopted by the Secretary. If an ONC–ATCB chooses to offer testing and certification options that specify additional requirements as a matter of its own business practices, we expect that in accordance with Guide 65, section 6, the ONC–ATCB would "give due notice of any changes it intends to make in its requirements for certification" and "take account of views expressed by interested parties before deciding on the precise form and effective date of the changes."

We note, however, that while we do not preclude an ONC–ATCB from certifying HIT in accordance with its own requirements that may be unrelated to and potentially exceed the certification criteria adopted by the Secretary, such activities are not within the scope of an ONC–ATCB's authority granted under the temporary certification program and are not endorsed or approved by the National Coordinator or the Secretary. Accordingly, we have added as a component of a new principle in the Principles of Proper Conduct for ONC–ATCBs (discussed in more detail in section *O. Validity of Complete EHR and EHR Module Certification and Expiration of Certified Status*) that any certifications issued to HIT that would constitute a Complete EHR or EHR Module and based on the applicable certification criteria adopted by the Secretary at subpart C must be separate and distinct from any other certification(s) that are based on other criteria or requirements. To further clarify, HIT which constitutes a Complete EHR or EHR Module that is tested and certified to the certification criteria adopted by the Secretary as well as an ONC–ATCB's own certification criteria would need to have its certified status as a Complete EHR or EHR Module noted separately and distinctly from any other certification the ONC–ATCB may issue based on the successful demonstration of compliance with its own certification criteria. For example, an ONC–ATCB should indicate that the HIT has been certified as a "Complete

EHR in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services" and, if applicable, separately indicate that the HIT meets "XYZ certification criteria as developed and/or required by [specify certification body]."

2. Types of Testing and Certification

We proposed in section 170.410 that applicants for ONC–ATCB status may seek authorization from the National Coordinator to perform Complete EHR testing and certification and/or EHR Module testing and certification.

We received multiple comments on the types of testing and certification that ONC–ATCBs can and should perform. Many of these comments were in response to our requests for public comments on whether ONC–ATCBs should test and certify the integration of EHR Modules and on whether applicants should be permitted to apply to either test and certify only Complete EHRs designed for an ambulatory setting or Complete EHRs designed for an inpatient setting.

a. Complete EHRs and EHR Modules

We proposed that potential applicants have the option of seeking authorization from the National Coordinator to perform Complete EHR testing and certification and/or EHR Module testing and certification.

Comments. We received comments expressing support for our proposal because of the flexibility it would provide to applicants and the industry. We also received a few comments expressing positions contrary to our proposal. One commenter recommended that we add more flexibility by allowing applicants, similar to our proposals for the proposed permanent certification program, to either do only testing or certification. Conversely, a few commenters recommended that we not give applicants the option to select, but instead require ONC–ATCBs to perform testing and certification for both Complete EHRs and EHR Modules. One commenter wanted us to ensure that there were at least two ONC–ATCBs for both Complete EHR and EHR Module testing and certification.

Response. We have attempted to create a temporary certification program that allows for as many qualified applicants to apply and become authorized as possible in the limited time allotted under the temporary certification program. We do not agree with the commenters that recommended that we pattern the applicant requirements after the proposed permanent certification program or that we ensure that there will be at least two ONC–ATCBs for both Complete EHR and EHR Module testing and certification. As discussed in the Proposed Rule, the temporary certification program's processes and requirements are different than the permanent certification program because of the urgency with which the temporary certification program must be established. We are also unable to ensure that there will be any specific number of ONC–ATCBs. We believe it is best to let the marketplace dictate the amount of qualified applicants that will apply for ONC–ATCB status. We are, however, confident that there are sufficient incentives for applicants to apply and that the program is structured in a manner that will maximize the number of qualified applicants.

b. Complete EHRs for Ambulatory or Inpatient Settings

We requested public comment in the Proposed Rule on whether the National Coordinator should permit applicants to seek authorization to test and certify only Complete EHRs designed for an ambulatory setting or, alternatively, Complete EHRs designed for an inpatient setting. Under our proposal, an applicant seeking authorization to perform Complete EHR testing and certification would be required to test and certify Complete EHRs designed for both ambulatory and inpatient settings.

Comments. We received comments ranging from support for providing the option for applicants to test and certify Complete EHRs for either ambulatory or inpatient settings to support for our proposal to require an ONC–ATCB to perform testing and certification for both settings. Some commenters thought that our proposal could stifle competition and expressed concern that there may not be enough entities capable of performing Complete EHR testing and certification for both settings. These commenters stated that allowing for Complete EHR testing and certification for either an ambulatory or inpatient setting could add competition and expedite certifications. Conversely, a few commenters stated that providing the option would multiply the National Coordinator's application workload and slow the authorization of ONC–ATCBs. One commenter also thought that the option may lead to applicants for ONC–ATCB status competing for limited resources, such as specialized staff for conducting testing and certification.

Some commenters expressed concern that if the National Coordinator were to allow applicants to test and certify Complete EHRs for either ambulatory or inpatient settings, there would not be enough ONC–ATCBs to test and certify Complete EHRs for each setting. Therefore, these commenters' support for the option was conditioned on the National Coordinator ensuring that there were an adequate number of ONC–ATCBs for each setting. One commenter only supported giving ONC–ATCBs an option to test and certify Complete EHRs for either ambulatory or inpatient settings if the option included testing and certification of EHR Module level interactions necessary for the exchange of data between ambulatory and inpatient Complete EHRs.

Some commenters stated that the option could lead to "almost complete" EHRs, which could then lead to eligible professionals and eligible hospitals paying large sums for niche EHR Modules based on complicated certification criteria such as biosurveillance or quality reporting. One commenter asserted that under our current proposal an applicant for ONC–ATCB status could seek authorization to test and certify EHR Modules that together would essentially constitute a Complete EHR for an ambulatory setting (or an inpatient setting). Therefore, the commenter contended that we should allow an applicant for ONC–ATCB status the option to seek authorization to test and certify Complete EHRs for either ambulatory or inpatient settings because an applicant for ONC–ATCB status could essentially choose that option by seeking all the necessary EHR Module authorizations for either ambulatory or inpatient settings.

Response. We believe that based on the concerns expressed by the commenters that it would be inappropriate at this time to allow applicants for ONC–ATCB status to seek authorization for the testing and certification of Complete EHRs for either ambulatory settings or inpatient settings. We will, however, reconsider this option for the permanent certification program based on the comments received on the proposed permanent certification program.

To address the commenters' concerns about "almost complete" EHRs, we want to reiterate that for EHR technology to be considered a Complete EHR it would have to meet *all* applicable certification criteria adopted by the Secretary. For example, a Complete EHR for an ambulatory setting would have to meet all certification criteria adopted at § 170.302 and § 170.304. Therefore, if we had provided the option for ONC–ATCBs to seek authorization to test and certify Complete EHRs for either ambulatory or inpatient settings, the Complete EHRs that ONC–ATCBs tested

and certified would have had to meet all the applicable certification criteria adopted by the Secretary.

We agree with the one commenter that an applicant for ONC–ATCB status could seek authorization to test and certify EHR Modules that together would potentially cover all the applicable certification criteria for an ambulatory setting. In fact, in relation to the privacy and security testing and certification of EHR Modules, we state in this final rule that if EHR Modules are presented for testing and certification as an integrated bundle that would otherwise constitute a Complete EHR we would consider them a Complete EHR for the purposes of being certified by an ONC–ATCB. The important distinction between the commenter's suggested approach and the option we proposed is that under the commenter's approach the ONC–ATCB would not be able to issue a "Complete EHR certification" for a combination of EHR Modules because the ONC–ATCB had not received authorization to test and certify Complete EHRs. Consequently, if a Complete EHR developer wanted to obtain Complete EHR certification, they could not seek such certification from an ONC–ATCB that did not have authorization to grant Complete EHR certifications. We would assume that a potential applicant for ONC–ATCB status would consider this impact on its customer base when determining what type of authorization to seek.

c. Integrated Testing and Certification of EHR Modules

In the Proposed Rule, we requested public comment on whether ONC–ATCBs should be required to test and certify that any EHR Module presented by one EHR Module developer for testing and certification would properly work (*i.e.,* integrate or be compatible) with other EHR Modules presented by different EHR Module developers.

Comments. Multiple commenters stated that testing and certifying EHR Modules to determine whether they can integrate with one another is a worthwhile endeavor. These commenters stated that such testing and certification would make it easier for eligible professionals and eligible hospitals to purchase certified EHR Modules that are compatible and could be used together to achieve meaningful use and could increase or improve interoperability among HIT in general. Conversely, many other commenters strongly disagreed with requiring EHR Modules to be tested and certified for compatibility. Overall, these commenters asserted that it would be technically infeasible as well as both logistically (*e.g.,* multiple testing and certification sites and multiple EHR Module developers) and financially impractical to attempt to test and certify for integration given the huge and shifting numbers of possible combinations. Some commenters, however, suggested that EHR Modules could be tested and certified as integrated bundles. One commenter recommended that if we were to pursue any type of EHR Module-to-EHR Module integration, it should be no earlier than when we adopt the next set of standards, implementation specifications, and certification criteria, and then it should only be done selectively based on meaningful use requirements. Another commenter suggested that ONC–ATCBs be given the option, but not be required, to determine if EHR Modules are compatible.

Response. We believe that the testing and certification of EHR Modules for the purposes of integration is inappropriate for the temporary certification program due to various impracticalities. We believe that EHR Module-to-EHR Module integration is inappropriate primarily because of the impracticalities pointed out by commenters related to the numerous combinations of EHR Modules that will likely exist and the associated technical, logistical, and financial costs of determining EHR Module-to-EHR Module integration. To the extent that an EHR Module developer or developers present EHR Modules together as an integrated bundle for testing and certification, we would allow the testing and certification of the bundle only if it was capable of meeting all the applicable certification criteria and would otherwise constitute a Complete EHR. In all other circumstances, we would not require testing and certification for EHR Module-to-EHR Module integration as part of the temporary certification program. Nothing in this final rule precludes an ONC–ATCB or other entity from offering a service to test and certify EHR Module-to-EHR Module integration. However, to be clear, although we do not require or specifically preclude an ONC–ATCB from testing and certifying EHR Module-to-EHR Module integration, any EHR Module-to-EHR Module testing and certification done by an ONC–ATCB or other entity will be done so without specific authorization from the National Coordinator and will not be considered part of the temporary certification program. We understand that testing and certification for EHR Module-to-EHR Module integration may be advantageous in certain instances, but we do not believe, for the reasons discussed above, that we could set all the necessary parameters for testing EHR Module-to-EHR Module integration within the allotted timeframe of the temporary certification program.

E. Application Process

As outlined in greater detail below, the proposed application process consisted of an applicant abiding by certain prerequisites before receiving an application, adhering to the application requirements and submitting the application by one of the proposed methods.

1. Application Prerequisite

We proposed in section 170.415 that applicants would be required to request, in writing, an application for ONC–ATCB status from the National Coordinator. We further proposed that applicants must indicate the type of authorization sought pursuant to § 170.410, and if seeking authorization to perform EHR Module testing and certification, the specific type(s) of EHR Module(s) they seek authorization to test and certify. Finally, we proposed that applicants would only be authorized to test and certify the types of EHR Modules for which the applicants sought and received authorization.

Comments. A commenter expressed agreement with our proposal to limit an applicant's authorization to test and certify EHR Modules to the EHR Modules specified in the applicant's application. The commenter requested, however, that we establish a process for allowing ONC–ATCBs to apply for additional authorization to test and certify additional EHR Modules and to allow for the expansion of authorization over time. Another commenter asked that we clarify that ONC–ATCBs that choose to only test and certify EHR Modules be allowed to limit their testing and certification to one health care setting, such as testing and certifying a "laboratory" EHR Module solely for an ambulatory setting.

Response. The only process that we intend to use to authorize ONC–ATCBs under the temporary certification program is the application process that we have proposed. Therefore, if an ONC–ATCB authorized to test and certify a certain type(s) of EHR Module(s) wanted to seek additional authorization for the testing and certification of other types of EHR Modules, it would need to submit another application requesting that specific authorization. We would

anticipate in that situation, however, that the application process and review would proceed fairly quickly. In addition, we will consider whether an alternative method would be appropriate for such a situation under the proposed permanent certification program. Lastly, we note, in response to a commenter's question about whether an ONC–ATCB authorized to test and certify a certain type of EHR Module is required to test and certify for both ambulatory and inpatient settings, that the answer would depend on what type of EHR Module authorization the applicant for ONC–ATCB status sought. As previously noted, it is possible to seek authorization to test and certify EHR Modules that address only an ambulatory or inpatient setting. Accordingly, we are finalizing this provision without modification.

2. Application

We proposed in section 170.420 that the application for ONC–ATCB status would consist of two parts. We further proposed that applicants would be required to complete both parts of the application and submit them to the National Coordinator for the application to be considered complete.

a. Part 1

In Part 1 of the application, we proposed that an applicant provide general identifying information including the applicant's name, address, city, state, zip code, and Web site. We proposed that an applicant also designate an authorized representative and provide the name, title, phone number, and e-mail address of the person who would serve as the applicant's point of contact. We proposed that an applicant complete and submit self audits to all sections of Guide 65 and ISO/IEC 17025:2005 (ISO 17025) as well as submit additional documentation related to Guide 65 and ISO 17025. We also proposed that an applicant had to agree to adhere to the Principles of Proper Conduct for ONC–ATCBs.

Comments. We received several comments expressing agreement with the application requirements, including the use of Guide 65 and ISO 17025. One commenter specifically stated that requiring applicants for ONC–ATCB status to demonstrate their conformance to both Guide 65 and ISO 17025 is an appropriate and effective means to demonstrate an applicant's competency and ability to test and certify Complete EHRs and/or EHR Modules and, therefore, an appropriate means for initiating our proposed testing and certification program. However, we also received multiple comments requesting that we provide more explanation about Guide 65 and ISO 17025. The commenters requested information about how Guide 65 and ISO 17025 are related to Complete EHRs and EHR Modules, why we selected Guide 65 and ISO 17025 as conformance requirements for the temporary certification program, and how Guide 65 and ISO 17025 are related to one another, including explaining why ISO 17025 is appropriate for the temporary certification program but not for the permanent certification program. Commenters also recommended that we consult with NIST to develop an "information paper" or other supplemental guidance document to assist the industry with understanding Guide 65 and ISO 17025 and how they will apply to the certification programs.

One commenter stated that conformance to ISO 17025 was not a barrier to entry because there are at least two commercial laboratories currently accredited to ISO 17025 and performing testing in a similar government program (USGv6 Testing Program). Conversely, other commenters expressed concern that Guide 65 and ISO 17025 were possible barriers to entry. Some commenters thought that the documentation requirements would be too high an administrative burden for applicants, while others thought there was not enough time for applicants to demonstrate compliance with Guide 65 and ISO 17025 in time to apply for, and receive authorization, under the temporary certification program.

The commenters offered various recommendations for addressing their stated concerns. One commenter suggested that we delay compliance with Guide 65 and ISO 17025 until the permanent certification program is implemented. A second option recommended by commenters was to not require strict compliance with Guide 65 and ISO 17025, but rather allow for material compliance. In support of this recommendation, one commenter contended that certain provisions of ISO 10725 (*i.e.,* provisions on uncertainty of measurements, sampling, calibration methods, and environmental conditions that impact results) do not appropriately address HIT testing and therefore should not apply. A third option presented by commenters was for us to embrace a glide path that would allow qualified organizations to move towards compliance in a systematic way. A more specific recommendation illustrating this sentiment was to allow applicants for ONC–ATCB status to meet certain requirements on a timeline that would enable a new entrant to build and demonstrate their capabilities throughout the application process while still requiring full adherence to the application requirements before an applicant is granted ONC–ATCB status.

Response. With respect to those comments that requested further explanation about Guide 65 and ISO 17025, we would note that the International Organization for Standardization (ISO) developed both standards. As explained in the Introduction of Guide 65, the observance of the Guide's specifies requirements is intended to ensure that certification bodies operate third-party certification systems in a consistent and reliable manner, which will facilitate their acceptance on a national and international basis. ISO 17025 is also an international standard intended to serve as a basis for accreditation, which accreditation bodies use when assessing the competence of testing and calibration laboratories. We note that both standards have been developed by a voluntary consensus standards body, as required by the National Technology Transfer and Advancement Act of 1995 and the Office of Management and Budget (OMB) Circular A–119, and we are aware of no alternative voluntary consensus standards that would serve the purpose for which these standards are intended to serve.

Guide 65 will be utilized to determine if an applicant for ONC–ATCB status is capable of conducting an appropriate certification program for certifying Complete EHRs and/or EHR Modules. ISO 17025 will be utilized to determine if an applicant for ONC–ATCB status is capable of conducting an appropriate testing program for testing Complete EHRs and/or EHR Modules. We believe that Guide 65 and ISO 17025 are clear in the requirements they impose on a testing and certification body, and therefore, we do not see the need for an "information" paper or additional guidance at this time. We would, as appropriate, consider issuing guidance to further clarify any requirements of this final rule.

We agree with the commenters that stated that our application requirements for the temporary certification program are appropriate and do not constitute a barrier to entry. As stated by commenters, requiring applicants for ONC–ATCB status to demonstrate their conformance to both Guide 65 and ISO 17025 is an appropriate and effective method for determining an applicant's competency and ability to test and certify Complete EHRs and/or EHR Modules and, therefore, an appropriate method for initiating our proposed

temporary certification program. By proposing these requirements, we have not only indicated that we believe them to be appropriate measures of applicants' competencies, but that they are also not overly burdensome and that applicants will have sufficient time to meet the requirements in time to apply under the temporary certification program. As we noted in the Proposed Rule, applicants under the permanent certification program may have to meet potentially more comprehensive requirements in order to meet the proposed accreditation requirement. In regard to the commenter's question about the application of ISO 17025 to the proposed permanent certification program, we have proposed that a separate accreditation process for testing laboratories would exist through the National Voluntary Laboratory Accreditation Program (NVLAP) and anticipate that process would include compliance with ISO 17025.

By ensuring that an ONC–ATCB is capable of performing its responsibilities related to testing and certification we believe industry and consumer confidence will be established in the temporary certification program and in the Complete EHRs and EHR Modules tested and certified under the program. Based on these reasons and our stated belief that there is sufficient time for an applicant to apply for ONC–ATCB status, we do not believe that any type of application or authorization process that would provide for any less than full achievement and compliance with the application requirements of the temporary certification program is appropriate, including allowing for material compliance or a glide path to full compliance. As to the one commenter's contention that certain provisions of ISO 17025 do not apply to the testing of HIT, it is incumbent upon an applicant for ONC–ATCB status to demonstrate in its self audit to ISO 17025 and/or Guide 65 why provisions or requirements do not apply to its request for authorization to test and certify Complete EHRs and/or EHR Modules.

We are finalizing this provision without modification.

b. Part 2

We proposed for Part 2 of the application that an applicant must submit a completed proficiency examination. We did not receive any comments on this provision. Therefore, we are finalizing this provision without modification.

3. Principles of Proper Conduct for ONC–ATCBs

We received multiple comments on the proposed Principles of Proper Conduct for ONC–ATCBs. We did not, however, receive any comments on the Principles of Proper Conduct proposed in paragraphs (c), (d) and (f) of § 170.423. Therefore, we are finalizing these Principles of Proper Conduct without modification. While we received comments on all the other proposed Principles of Proper Conduct for ONC–ATCBs and suggestions for additional principles of proper conduct, the majority of the comments were focused on compliance with Guide 65 and ISO 17025, the proposed use of NIST test tools and test procedures, the requirement that ONC–ATCBs provide ONC, no less frequently than weekly, a current list of Complete EHRs and EHR Modules that have been tested and certified, the proposed records retention requirement, and our proposed requirement that ONC–ATCBs issue refunds for tests and certifications that were not completed.

a. Operation in Accordance With Guide 65 and ISO 17025 Including Developing a Quality Management System

We proposed in section 170.423(a) that an ONC–ATCB would be required to operate its certification program in accordance with Guide 65 and its testing program in accordance with ISO 17025. We also proposed in § 170.423(b) that an ONC–ATCB be required to maintain an effective quality management system which addresses all requirements of ISO 17025.

The comments we received on Guide 65 and ISO 17025 were repetitive and essentially indistinguishable from the comments we received on Guide 65 and ISO 17025 in relation to our proposed application process. Therefore, we do not discuss them again in this section and we are finalizing this Principle of Proper Conduct for ONC–ATCBs without modification.

b. Use of NIST Test Tools and Test Procedures

We proposed in section 170.423(e), that an ONC–ATCB would be required to "[u]se testing tools and procedures published by NIST or functionally equivalent testing tools and procedures published by another entity for the purposes of assessing Complete EHRs and/or EHR Modules compliance with the certification criteria adopted by the Secretary."

We received a number of comments on this proposed Principle of Proper Conduct for ONC–ATCBs. We have divided the comments into two categories, which are: Establishment of test tools and test procedures; and public feedback process.

i. Establishment of Test Tools and Test Procedures

Comments. While some commenters expressed agreement with the use of NIST test tools and test procedures, many commenters requested clarification on NIST's role and scope of authority. A commenter specifically asked whether NIST would be the author of both the test tools and test procedures for each and every certification criterion. Other commenters requested clarification of the phrase "functionally equivalent testing tools and procedures published by another entity" and specifically requested that we create a process for the timely establishment of functionally equivalent test tools and test procedures, with one commenter recommending that "functionally equivalent" be determined by ONC during the application process. Commenters noted that NIST has published draft versions of test procedures that will likely change once the final rules for both the HIT Standards and Certification Criteria interim final rule and the CMS Medicare and Medicaid EHR Incentive Programs proposed rule are issued. One commenter concluded that "functionally equivalent" would not be able to be determined until the final NIST test procedures are issued. To address this issue, the commenter recommended that we adopt CCHIT "IFR Stage 1 Certification" procedures (with appropriate modifications once a final rule is published) for testing at the start of the temporary certification program and that ONC–ATCBs use NIST test procedures once they became available at which point the NIST test procedures could serve as an option for the temporary certification program, and subsequently be deemed the only acceptable set of test procedures for the proposed permanent certification program. Another commenter expressed a lack of confidence in functionally equivalent test tools and test procedures and requested that we confirm that Complete EHR and EHR Module developers would have no liability regarding the functional equivalence of an ONC–ATCB's test tools and test procedures. The commenter stated that if this assurance could not be provided then only NIST test tools and test procedures should be utilized. Commenters also asked for clarification on the extent to which ONC–ATCBs are permitted to modify test procedures/test

scripts and how test procedures/test scripts could be corrected, if necessary. Some commenters expressed a preference for consistency of test data and test criteria across all testing organizations and were concerned about allowing ONC–ATCBs to define their own test scripts or test procedures. The commenters reasoned that some ONC–ATCBs may have "easier" tests than others, and therefore, the credibility of the process will be uneven and questionable. Finally, a commenter also asked who would develop implementation guidance for standards adopted in the HIT Standards and Certification Criteria interim final rule and how this guidance would be linked to the test methods in a way that would accurately reflect a common interpretation of a standard.

Response. First and foremost, we reiterate that the National Coordinator is responsible for administering the temporary certification program. Consistent with the HITECH Act, we are in consultation with NIST to learn from its resident experts and have requested NIST's assistance in the development of test tools and test procedures that all ONC–ATCBs could use to properly and consistently test and certify Complete EHRs and EHR Modules in accordance with the standards, implementation specifications, and certification criteria adopted by the Secretary. We expect that NIST will develop a test tool and test procedure for each and every certification criterion.

We have reviewed the commenters' concerns and requests for clarification. After further consideration, we have decided to modify this Principle of Proper Conduct for ONC–ATCBs to more thoroughly clarify our intent. We have revised the Principle of Proper Conduct for ONC–ATCBs to remove the concept of "functionally equivalent" and to clearly state that the National Coordinator would play the central role in determining which test tools and test procedures will be approved for ONC–ATCBs to use. The revised Principle of Proper Conduct requires ONC–ATCBs to "[u]se test tools and test procedures approved by the National Coordinator for the purposes of assessing Complete EHRs' and/or EHR Modules' compliance with the certification criteria adopted by the Secretary."

We believe that this revision provides the National Coordinator with greater flexibility and discretion to ensure that Complete EHRs and EHR Modules are being tested and certified by ONC–ATCBs according to the best test tools and test procedures available. In that regard, we believe that NIST test tools and test procedures will likely be a primary source for ONC–ATCBs to use as they develop their test scripts. We understand that NIST may establish test tools and test procedures based on multiple sources, such as NIST-developed tools, industry-developed tools, or open source tools, as appropriate. NIST has been exploring and will likely utilize all three of these options. That being said, this revised Principle of Proper Conduct for ONC–ATCBs will provide the National Coordinator with the ability to approve not only NIST test tools and test procedures, but potentially other test tools and test procedures that are identified or developed by other organizations. We understand that commenters would prefer to have the National Coordinator serve as the locus of control with respect to which test tools and test procedures ONC–ATCBs are permitted to use. We also inferred from the comments that such an approach would provide greater certainty to Complete EHR and EHR Module developers as to which test tools and test procedures may be used by ONC–ATCBs, as well as greater consistency among ONC–ATCBs' testing and certification processes.

A person or entity may submit a test tool and/or test procedure to the National Coordinator to be considered for approval to be used by ONC–ATCBs. The submission should identify the developer of the test tool and/or test procedure, specify the certification criterion or criteria that is/are addressed by the test tool and/or test procedure, and explain how the test tool and/or test procedure would evaluate a Complete EHR's or EHR Module's compliance with the applicable certification criterion or criteria. The submission should also provide information describing the process used to develop the test tool and/or test procedure, including any opportunity for the public to comment on the test tool and/or test procedure and the degree to which public comments were considered. In determining whether to approve a test tool and/or test procedure, the National Coordinator will consider whether it is clearly traceable to a certification criterion or criteria adopted by the Secretary, whether it is sufficiently comprehensive (assesses all required capabilities) for ONC–ATCBs to use in testing and certifying a Complete EHR's or EHR Module's compliance with the certification criterion or criteria adopted by the Secretary, whether an appropriate public comment process was used during the development of the test tool and/or test procedure, and any other relevant factors. When the National Coordinator has approved test tools and/or test procedures, we will publish a notice of availability in the **Federal Register** and identify the approved test tools and test procedures on the ONC Web site.

Once test tools and test procedures have been approved by the National Coordinator, ONC–ATCBs will have the responsibility and flexibility to configure their own test scripts (*i.e.,* specific scenarios using the test tools and test procedures), to create, for example, a testing sequence that an ONC–ATCB believes is the most efficient way for testing a certain suite of capabilities. Given the level and type of adjustments that we expect ONC–ATCBs to make, we do not believe that it will be possible for ONC–ATCBs to include significant variations in their test scripts such that a Complete EHR or EHR Module will pass a test administered by one ONC–ATCB but fail a test administered by a different ONC–ATCB. As to the commenter's inquiry about how "implementation guidance" will link to test tools and test procedures, we believe that, where implementation specifications have been adopted in the HIT Standards and Certification Criteria interim final rule, they will be considered in the development of test tools and test procedures.

Comments. A commenter recommended, based on the increased focus on the safety of EHRs, that the NIST testing framework be developed using auditable quality guidelines, including documentation on the purpose, installation, configuration, use and traceability of the NIST testing framework. Some commenters provided recommendations on the processes for the development of test tools and test procedures. A commenter suggested that NIST look to adopt existing test tools and test procedures currently operational and developed via industry consensus, while other commenters specifically recommended that we utilize HL7 EHR–S FM and its profiles and the Committee on Operating Rules for Information Exchange® (CORE) testing processes. Other commenters contended that the scope of the test procedures currently developed by NIST is too narrow and does not take into account clinical realities when systems are implemented in a clinical setting. Another commenter recommended that the test tools and test procedures support end-user needs.

Response. The NIST test tools and test procedures include components to help ensure traceability of a specific certification criterion. The test tools and test procedures also have

documentation for installation, configuration and use. As noted above, the National Coordinator may approve test tools and test procedures for the temporary certification program based on multiple sources, as appropriate. We would further note that while we recognize the utility of other sources, such as HL7 EHR–S FM or CORE testing processes, the temporary certification program's primary focus is to test and certify Complete EHRs and EHR Modules to the certification criteria adopted by the Secretary. The scope of the test tools and test procedures is defined by the applicable certification criterion or criteria. Therefore, the test tools and test procedures are not currently focused on addressing matters outside the scope of adopted certification criteria such as usability or "end-user needs."

ii. Public Feedback Process

Comments. Commenters expressed concern that there was a lack of a specified process for stakeholders, particularly Complete EHR and EHR Module developers, to participate in the development, review and validation of test procedures. Multiple commenters asked for a formal role for Complete EHR and EHR Module developers as well as eligible professionals and eligible hospitals to give feedback to NIST. A commenter noted that the Proposed Rule stated that the test tools and test procedures would be published by NIST on its Web site or through a notice in the **Federal Register,** but that the Proposed Rule did not clearly delineate the processes, how the processes will be managed, and a timeline. Another commenter stated that when "test scripts" involve or relate to the implementation of an adopted standard, NIST should be required to consult with the standards development organization (SDO) publisher of the standard for review of proposed "test scripts," and should be required to consider comments made by the SDO prior to publication of final "test scripts." A final comment expressed concern that the test tools and test procedures being developed by NIST are not following the government protocol for openness and transparency by allowing for an open, public comment period on the test tools and test procedures before adoption.

Response. We noted in the Proposed Rule that the test tools and test procedures would be published in some manner and suggested, as examples, that publication on NIST's Web site or by notice in the **Federal Register** would be acceptable methods. As noted above, NIST has published drafts of the test tools and test procedures on its Web site and has been accepting and reviewing public comments since releasing the drafts. Specifically, NIST began publishing test tools and test procedures on its Web site on February 23, 2010. The test tools and test procedures have been published in four "waves" or groups of test tools and test procedures. At the time this final rule was prepared, NIST had received over 100 public comments on its drafts. In response, NIST has issued revised drafts of the test tools and test procedures and is developing "frequently asked questions and answers" that it plans to post on its Web site to address common comments on the draft test tools and test procedures. NIST intends to continue to seek and consider public feedback until the test tools and test procedures are finalized, which will likely occur in conjunction with the publication of the final rules for both the HIT Standards and Certification Criteria interim final rule and the Medicare and Medicaid EHR Incentive Programs proposed rule.

It is not within the scope of this rulemaking to instruct NIST to consult with other entities. However, we note that all stakeholders, including Complete EHR and EHR Module developers and SDO publishers, may participate in the public comment process described above. Furthermore, we believe that the feedback process currently employed by NIST is an appropriate and acceptable method for soliciting, accepting and meaningfully considering public comments on the test tools and test procedures.

c. ONC Visits to ONC–ATCB Sites

We proposed in section 170.423(g) to require an ONC–ATCB to allow ONC, or its authorized agent(s), to periodically observe on site (unannounced or scheduled), during normal business hours, any testing and/or certification performed to demonstrate compliance with the requirements of the temporary certification program.

Comments. A commenter stated that if visits are unannounced, then there can be no assurance that a test or certification will actually be underway upon arrival of an ONC representative. Therefore, the commenter recommended that we should revise the requirement to require that an ONC–ATCB respond within 2 business days to an ONC request to observe testing and/or certification by providing the date, time, and location of the next scheduled test or certification. The commenter further stated that ONC observers for site visits would likely need to execute confidentiality and/or business associate agreements because some HIT vendors treat their software screens and other elements as trade secrets. Additionally, the commenter stated that during site testing of hospital-developed EHRs, protected health information may inadvertently appear on screen in reports or audit trails. The commenter contended that if ONC or its authorized agent(s) were unable to execute such confidentiality and/or business associate agreements, then ONC observation may have to be limited to those elements of testing that do not risk revealing vendor trade secrets or protected health information; or ONC might have observation of testing limited to Complete EHR or EHR Module developers who waive their confidentiality requirements for ONC observers.

Response. Our original proposal gave us the option to either conduct scheduled or unannounced visits. After considering the comments, we believe it is appropriate to maintain both options. If we determine that there is a specific testing and/or certification that would be appropriate for us or our authorized agent(s) to observe, we may find it is more prudent to schedule a visit. However, to monitor compliance with the provisions of the temporary certification program and to maintain the integrity of the program, we believe that unannounced visits are appropriate. In addition, we expect that any confidentiality agreement executed between an ONC–ATCB and a customer, such as Complete EHR and EHR Module developers, for the purposes of testing and certification under the temporary certification program would include ONC and its authorized representatives as parties who may observe the testing and certification of the customer's Complete EHR or EHR Module. We would also expect that the confidentiality agreement would cover any proprietary information, trade secrets, or protected health information. Therefore, we are finalizing this Principle of Proper Conduct without modification.

d. Lists of Tested and Certified Complete EHRs and EHR Modules

i. ONC–ATCB Lists

We proposed in section 170.423(h) to require an ONC–ATCB to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been tested and certified which includes, at a minimum, the vendor name (if applicable), the date certified, product version, the unique certification number or other specific product identification, and where applicable, the certification criterion or

certification criteria to which each EHR Module has been tested and certified.

Comments. Many provider organizations expressed appreciation for the proposed requirement and the proposed frequency for which the lists were to be updated. In relation to what ONC–ATCBs report, a commenter specifically expressed support for making timely, complete, and useful information available to eligible professionals and eligible hospitals as they work to purchase and implement Certified EHR Technology that will enable them to demonstrate meaningful use.

Some commenters requested clarification and made recommendations for revisions to the provision. One commenter suggested that the provision should be revised to require an ONC–ATCB to notify ONC within a week of successful testing and certification of new Complete EHRs and/or EHR Modules. Additionally, the commenter contended that the proposed provision was unclear as to whether an ONC–ATCB was required to send a complete, current list or only new additions and whether the list could be sent via e-mail. Another commenter suggested revising the provision to require an ONC–ATCB to also report a current list of "applicants" and their status in the testing or certification queue.

Response. We will, as proposed, require that ONC–ATCBs provide the National Coordinator with a current list of Complete EHRs and/or EHR Modules that have been tested and certified no less frequently than weekly. We anticipate only requiring weekly updates, but ONC–ATCBs are free to provide more frequent updates. We believe that weekly updates are sufficient for providing current information to the market on the status of Complete EHRs and EHR Modules without placing an administrative burden on ONC–ATCBs. In this regard, we have previously stated and continue to expect that the information would be provided electronically, such as through e-mail. We also agree with the commenter that it would be unnecessary for an ONC–ATCB to continue to report on previously certified Complete EHRs and/or EHR Modules and, therefore, only expect these weekly reports to include new certifications issued between the last weekly report and the newly submitted weekly report. Additionally, we do not believe that any substantial benefit would come from having an ONC–ATCB report on the status of Complete EHRs and/or EHR Modules currently being tested and certified. The time needed for testing and certification of Complete EHRs and EHR Modules will likely vary based on many factors and, in some cases, may not be completed due to various reasons. Therefore, we do not believe that the reporting of products in an ONC–ATCB's queue should be a requirement at this time.

We agree with the commenter who indicated that useful information should be made available to eligible professionals and eligible hospitals as they decide which Certified EHR Technology to adopt. Moreover, we note that much of the information reported by ONC–ATCBs will be included in the Certified HIT Products List (CHPL) that will be available on ONC's Web site. After consideration of public comments and our own programmatic objectives, we accordingly believe that two additional elements should be reported by ONC–ATCBs in order to improve transparency and assist eligible professionals and eligible hospitals who seek to adopt certified Complete EHRs and EHR Modules. The two additional elements we will require ONC–ATCBs to report are the clinical quality measures to which a Complete EHR or EHR Module has been tested and certified and, where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary. As with the other information that ONC–ATCBs must report, these two additional elements, as suggested by the commenter, will enable eligible professionals and eligible hospitals to make informed purchasing decisions.

The reporting of clinical quality measures to which a Complete EHR or EHR Module has been tested and certified will enable an eligible professional or eligible hospital to identify and adopt a Complete EHR or EHR Module that includes the clinical quality measures they seek to implement. Knowledge of the additional software a Complete EHR or EHR Module has relied upon to demonstrate compliance with a certification criterion or criteria will be useful, and in some cases essential, for eligible professionals and eligible hospitals who are deciding which Complete EHR or EHR Module to adopt. With this information, eligible professionals and eligible hospitals would be able to assess whether a specific certified Complete EHR or EHR Module may be incompatible with their current information technology (IT) or would require them to install additional IT. We stress that this reporting requirement only relates to software that is *relied upon* by a Complete EHR or EHR Module to demonstrate compliance with a certification criterion or criteria adopted by the Secretary. We do not intend or expect this requirement to be construed as a comprehensive specifications list or similar type of inclusive list. Rather, our rationale for including this requirement is to ensure that eligible professionals and eligible hospitals who adopt a certified Complete EHR or EHR Module understand what is necessary for the Complete EHR or EHR Module to operate in compliance with the certification criterion or criteria to which it was tested and certified.

For example, if a Complete EHR relied upon an operating system's automatic log-off functionality to demonstrate its compliance with this certification criterion, we would expect the operating system relied upon to be reported. Conversely, if a Complete EHR included its own automatic log-off capability, even though the Complete EHR may have been tested and certified on a particular operating system, we would *not require* the operating system to be reported because it was not relied upon to demonstrate compliance with the certification criterion.

Finally, we note that our required reporting elements constitute a minimum. We do not preclude ONC–ATCBs from including in their weekly reports additional information that prospective purchasers and users of Complete EHRs and EHR Modules would find useful, such as specifying the Complete EHR or EHR Module's compatibility with other software or compatibility with other EHR Modules. If not reported to the National Coordinator, we encourage ONC–ATCBs to consider making such information available on their own Web sites to better inform prospective purchasers and users of Complete EHRs and EHR Modules.

We are revising § 170.423(h) consistent with our discussion above.

ii. Certified HIT Products List

We stated in the Proposed Rule that in an effort to make it easier for eligible professionals and eligible hospitals to cross-validate that they have in fact adopted Certified EHR Technology, the National Coordinator intends to make a master CHPL of all Complete EHRs and EHR Modules tested and certified by ONC–ATCBs available on the ONC Web site. The CHPL would be a public service and would be a single, aggregate source of all the certified product information ONC–ATCBs provide to the National Coordinator. The CHPL would also represent all of the Complete EHRs and EHR Modules that could be used to meet the definition of Certified EHR

Technology. We also noted that, over time, we anticipate adding features to the Web site, which could include interactive functions to enable eligible professionals and eligible hospitals to determine whether a combination of certified EHR Modules could constitute Certified EHR Technology.

Comments. Many commenters expressed support for our decision to create a list of certified Complete EHRs and EHR Modules and to post a link to that list on our Web site. Many commenters also provided recommendations for how to enhance the list. One commenter endorsed an online system whereby physicians could type in or select information on the Complete EHR or EHR Module they planned on using to determine whether their selected combination would enable them to meet the CMS Medicare and Medicaid EHR Incentive Programs requirements. The commenter reasoned that the steps were necessary because eligible professionals, especially in smaller practices, did not have the technical expertise or support to ascertain whether or not a Complete EHR, EHR upgrades, EHR Module(s), or a combination of EHR Modules would enable them to perform the meaningful use requirements. Another commenter requested an explicit commitment from ONC that the use of certified Complete EHRs and/or EHR Modules on the CHPL will support their ability to report all required meaningful use measures.

Some commenters expressed a preference that the CHPL contain information on the capabilities of certified Complete EHRs and EHR Modules associated with adopted certification criteria. Other commenters requested that the CHPL contain information on whether certified Complete EHRs or EHR Modules are compatible with other HIT. In particular, commenters stated that it was important to eligible professionals and eligible hospitals for Complete EHR and EHR Module developers to fully disclose the functions for which their products are certified, which software components are necessary to meet certification criteria, and to also fully disclose any compatibility issues. A few commenters also suggested that the CHPL contain data on usability features of certified Complete EHRs and EHR Modules.

One commenter recommended that ONC and each ONC–ATCB maintain a list of certified Complete EHRs and EHR Modules. Another commenter recommended that, in order to prevent the conveyance of potentially inaccurate information and confusion in the market, an ONC–ATCB should not maintain on its own Web site a current list of the Complete EHRs and/or EHR Modules that it has certified, but instead reference the CHPL on ONC's Web site for the complete list of certified Complete EHRs and EHR Modules.

Response. We appreciate the commenters' support for the CHPL and their recommendations for its enhancement. We intend for the CHPL to be a single, aggregate source of all certified Complete EHRs and EHR Modules reported by ONC–ATCBs to the National Coordinator. The CHPL will comprise all of the certified Complete EHRs and EHR Modules that could be used to meet the definition of Certified EHR Technology. It will also include the other pertinent information we require ONC–ATCBs to report to the National Coordinator, such as a certified Complete EHR's version number. Eligible professionals and eligible hospitals that elect to use a combination of certified EHR Modules may also use the CHPL Web page to validate whether the EHR Modules they have selected satisfy all of the applicable certification criteria that are necessary to meet the definition of Certified EHR Technology. The CHPL Web page will include a unique identifier (such as a code or number) for each certified Complete EHR and each combination of certified EHR Modules that satisfies all of the applicable certification criteria necessary to meet the definition of Certified EHR Technology. The unique code or number listed on the CHPL Web page could subsequently be used to submit to CMS for attestation purposes.

We believe that only ONC should maintain the CHPL to ensure that the CHPL is accurate and comprehensive. However, we do not believe that it is appropriate to preclude an ONC–ATCB from maintaining on its own Web site a list of Complete EHRs and/or EHR Modules that it tests and certifies. An ONC–ATCB's own list could have benefits for the market in identifying the specific ONC–ATCB that tested and certified a Complete EHR or EHR Module. The ONC–ATCB may also create a link on its Web site to the CHPL, which conceivably would be a user-friendly feature.

e. Records Retention

We proposed in section 170.423(i) to require an ONC–ATCB to retain all records related to the testing and certification of Complete EHRs and/or EHR Modules for the duration of the temporary certification program and to provide copies of all testing and certification records to ONC at the sunset of the temporary certification program.

Comments. A commenter asserted that requesting "all" testing and certification records will lead to ONC receiving a voluminous amount of records that we likely never intended to receive. The commenter recommended that we be more specific about the records ONC–ATCBs will need to provide copies of to ONC.

Many commenters noted that CMS has proposed in its Medicare and Medicaid EHR Incentive Programs proposed rule to require providers to maintain records demonstrating meaningful use, which includes the use of Certified EHR Technology, for 10 years. The commenters noted that in the event of an audit, eligible professionals and eligible hospitals may need to go back to the certification body or ONC, in the case of the temporary certification program, to verify that a particular product was indeed certified at a particular point in time. Therefore, the commenters recommended that our proposed retention period for certification bodies needs to be equal to the length of time that eligible professionals and eligible hospitals must maintain records under CMS's proposal, plus two or more additional years to ensure that records are available during an audit process. A commenter also requested that ONC specify how long it would retain copies of records provided by ONC–ATCBs at the sunset of the temporary certification program.

Response. To address the commenter's concern about voluminous records being provided to ONC and to provide clarity to ONC–ATCBs about their records retention responsibility, we are clarifying the language of this Principle of Proper Conduct. For the duration of the temporary certification program, an ONC–ATCB will be required to retain all records related to tests and certifications in accordance with Guide 65 and ISO 17025. Upon the conclusion of testing and certification activities under the temporary certification program, ONC–ATCBs will be required to provide copies of the final results of all completed tests and certifications to ONC (*i.e.,* all passed and failed results). ONC will retain all records received from ONC–ATCBs in accordance with applicable federal law and may use the records for assessing compliance with temporary certification program requirements. Our records retention requirement should be construed as an independent requirement. Any other records retention requirements or potential legal compliance requirements should be complied with fully and not in association or correlation with our records retention requirements.

We are revising § 170.423(i) consistent with our discussion above.

f. Refunds

We proposed in section 170.423(j) to require an ONC–ATCB to promptly refund any and all fees received for tests and certifications that will not be completed.

Comments. While a vendor organization expressed agreement with our proposed refund requirement, potential applicants for ONC–ATCB status requested that we clarify that refunds would only be required where an ONC–ATCB's conduct caused the testing and certification to be incomplete as opposed to a Complete EHR or EHR Module developer's conduct or a Complete EHR's or EHR Module's failure to achieve a certification. One commenter asked whether this clause was meant to apply only when an ONC–ATCB had its status revoked. Another commenter suggested that our proposed requirement for ONC–ATCBs to return funds should also apply to situations where Complete EHR or EHR Module developers are required to recertify their products because of misconduct by an ONC–ATCB.

Response. We agree with the commenters that suggested our proposed refund requirement needs clarification. As advocated by the commenters, it was our intention to require ONC–ATCBs to issue refunds only in situations where an ONC–ATCB's conduct caused testing and certification to not be completed. We also agree with the one commenter that this would include situations where a Complete EHR or EHR Module is required to be recertified because of the conduct of an ONC–ATCB. Similarly, if an ONC–ATCB were to be suspended by the National Coordinator under the suspension provisions we have incorporated in this final rule, an ONC–ATCB would be required to refund all fees paid for testing and certification if a Complete EHR or EHR Module developer withdraws a request for testing and certification while the ONC–ATCB is under suspension.

We are revising § 170.423(j) consistent with our discussion above.

g. Suggested New Principles of Proper Conduct

We received a few comments that suggested we adopt additional principles of proper conduct. These comments concerned the impartiality and business practices of ONC–ATCBs.

Comments. A commenter recommended that applicants for ONC–ATCB status should be required to not have an interest, stake and/or conflict of interest in more than one entity receiving ONC–ATCB status nor have any conflict of interest with EHR product companies actively promoting EHR products in the marketplace.

Response. Applicants for ONC–ATCB status and ONC–ATCBs must adhere to the requirements of Guide 65 and ISO 17025. These requirements explicitly obligate testing and certification bodies to conduct business in an impartial manner. For instance, an applicant for ONC–ATCB status and/or an ONC–ATCB must have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity and must ensure that activities of related bodies do not affect the confidentiality, objectivity and impartiality of its certifications. We believe these provisions as well as other impartiality provisions contained in Guide 65 and ISO 17025 adequately address any potential conflicts of interest or other situations that might jeopardize the integrity of the temporary certification program.

Comments. We received a few comments recommending that ONC–ATCBs' business practices be considered and evaluated. In particular, one commenter recommended that we adopt a principle of proper conduct that requires an ONC–ATCB to establish, publish and adhere to a non-discriminatory protocol to ensure that requests for testing and certification are processed in a timely manner beginning on the date the ONC–ATCB sets for accepting requests for testing and certification. The commenter asserted that no one should be allowed to make a request prior to the date set by the ONC–ATCB and requests should be processed in the order in which they are received without regard to whether they are for Complete EHRs or EHR Modules. The commenter further asserted that in the event of simultaneously submitted requests, the National Coordinator should conduct a randomized, fair and transparent method for selecting the order in which the requests will be reviewed. Conversely, another commenter suggested that requests for testing and certification of Complete EHRs and/or EHR Modules that cover the largest market share should be processed first. One commenter recommended that all requests for testing and certification be required to be processed within six months of receipt by an ONC–ATCB.

Response. We have established the Principles of Proper Conduct for ONC–ATCBs. ONC–ATCBs must abide by these Principles of Proper Conduct to remain in good standing. As noted in the previous response, a Principle of Proper Conduct for ONC–ATCBs requires ONC–ATCBs to adhere to the provisions of Guide 65 and ISO 17025, which require an ONC–ATCB to have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity as well as have a documented structure that safeguards impartiality including provisions that ensure the impartiality of its operations. The National Coordinator will review the policies, procedures, and documented structure of applicants for ONC–ATCB status during the application process to ensure that a potential ONC–ATCB meets the impartiality requirements. An ONC–ATCB would also have to maintain impartiality in its operations to remain in good standing under the temporary certification program.

We believe that the requirements of Guide 65 and ISO 17025 clearly require ONC–ATCBs to develop an impartial process for handling requests for the testing and certification of Complete EHRs and EHR Modules. Guide 65 specifically states that "access shall not be conditional upon the size of the [Complete EHR or EHR Module developer] or membership [in] any association or group, nor shall certification be conditional upon the number of certificates already issued." As for the one commenter's recommendation that we require requests for testing and certification to be completed within six months, we will not adopt such a requirement. Due to factors such as the uncertainty of how many ONC–ATCBs will exist and how many requests for the testing and certification of Complete EHRs and EHR Modules will be received by each ONC–ATCB, we do not believe such a requirement would be equitable or enforceable.

4. Application Submission

We proposed in section 170.425 to allow an applicant for ONC–ATCB status to submit its application either electronically via e-mail (or web submission if available), or by regular or express mail at any time during the existence of the temporary certification program. We did not receive any comments on this provision. Therefore, we are finalizing this provision without modification.

5. Overall Application Process

We received a few comments regarding the overall application process.

Comment. One commenter suggested that applicants for ONC–ATCB status preferably be not-for-profit companies, while another commenter suggested that the number of applicants be limited to five.

Response. We believe it is appropriate to allow all qualified applicants to apply and obtain ONC–ATCB status. We believe that the more applicants that can obtain ONC–ATCBs status the more the market will benefit in terms of increased competition and more options for the testing and certification of Complete EHRs and EHR Modules. Restrictions on the number of applicants that can apply or requiring an applicant for ONC–ATCB status to be a not-for-profit entity will only limit these potential benefits.

Comment. A commenter recommended as part of the ONC–ATCB application process that an applicant indicate the testing site methods it is capable of supporting. The commenter reasoned that this would provide another basis for vendors to select an ONC–ATCB.

Response. An ONC–ATCB is required to provide the types of testing and certification methods that we have specified in § 170.457. We believe that an applicant will make such methods and any additional methods it offers known to the market as a means of attracting customers.

Comment. A commenter recommended that the temporary certification program serve as a "test bed" for the accreditation process so that the permanent certification program may limit the frequency with which applicants can reapply for ONC–ACB status.

Response. As discussed in the Proposed Rule, we are unable to establish an accreditation process for the temporary certification program due to the need to establish a certification program as soon as possible. Although we do not have sufficient time to establish an accreditation program, we believe that we have established sufficiently stringent requirements for ONC–ATCB applicants and ONC–ATCBs that, if an ONC–ATCB chose to apply for accreditation under the proposed permanent certification program, it would be well situated to successfully navigate the process.

F. Application Review, Application Reconsideration and ONC–ATCB Status

We proposed in the Proposed Rule to review an application for ONC–ATCB status and, in most circumstances, issue a decision within 30 days. We proposed that if an application was rejected and certain criteria were met, an applicant could seek reconsideration of the denial. We proposed that if an application were deemed satisfactory, we would make it publicly known that the applicant had achieved ONC–ATCB status and the ONC–ATCB would be able to begin testing and certifying consistent with the authorization granted by the National Coordinator. In association with these proposals, we specifically requested that the public comment on whether we should review an entire application at once or as proposed, in parts; and whether we should reconsider a twice deficient application for any reason besides a clear factual error.

1. Review of Application

We proposed in section 170.430 that we would review applications in the order in which we received them, that the National Coordinator would review Part 1 of the application and determine whether Part 1 of the application was complete and satisfactory before proceeding to review Part 2 of the application, and that the National Coordinator would issue a decision within 30 days of receipt of an application submitted for the first time.

We proposed that the National Coordinator would be able to request clarification of statements and the correction of inadvertent errors or minor omissions. We proposed that the National Coordinator would identify any deficiencies in an application part and provide an applicant with an opportunity to both correct any deficiencies and submit a revised application in response to a deficiency notice on each part of the application. We further proposed that if the National Coordinator determined that a revised application still contained deficiencies, the applicant would be issued a denial notice related to that part of the application. We proposed that the denial notice would indicate that the applicant would no longer be considered for authorization under the temporary certification program, but that the applicant could request reconsideration of the decision in accordance with § 170.435. In association with these proposals, we specifically requested that the public comment on whether it would be preferable for applicants to have their entire application reviewed all at once and then issued a formal deficiency notice or whether we should, as proposed, review applications in parts.

We proposed that an application would be deemed satisfactory if it met all the application requirements. We further proposed that once the applicant was notified of this determination, the applicant would be able to represent itself as an ONC–ATCB and begin testing and certifying Complete EHRs and EHR Modules consistent with its authorization.

Comments. A commenter requested that the National Coordinator clarify that an application will be deemed satisfactory based on the submission of an application that substantially or materially complied with the requirements set forth in regulation. Another commenter recommended that we develop an expeditious internal review and approval process for ONC–ATCB applications. The commenter suggested that this process include a fast-track reprocessing system, as necessary, to allow ONC–ATCB applicants to swiftly correct initial errors and deficiencies.

A commenter expressed agreement and support for the proposed process affording the National Coordinator discretion to request clarifications of statements or corrections of errors or omissions, but the commenter did not agree that such requests should be limited to only inadvertent or minor errors. The commenter reasoned that given the time constraints and complexity of the application process, the National Coordinator should be able to consider requesting clarifications or corrections in a collaborative process with applicants, as appropriate. The commenter also expressed general agreement with our proposal that an applicant be provided up to fifteen (15) days to respond to a formal deficiency notice. The commenter suggested, however, that considering the National Coordinator's opinion that few organizations will be able to meet the criteria in the temporary certification program, the National Coordinator should have the discretion to grant an extension beyond the 15 days upon a showing of good cause by the applicant. The commenter asserted that this proposal would provide flexibility and assist in ensuring that the process for approving ONC–ATCBs is successful.

We received two comments that expressed agreement with our proposal to review ONC–ATCB applications in parts and two comments recommending that we review the whole application before issuing a deficiency notice. One commenter recommended processing the application based on the request of the applicant or the needs of the reviewer. Both sides contended that their recommended method was more efficient and better for the applicant and reviewer. A couple of commenters requested that, if the review process were to remain a two part process, we make clear that each part of the application will be reviewed in its

entirety before a deficiency notice would be issued. One of the commenters also requested that we make clear that each part receives two review opportunities.

Response. We believe that applicants should be required to fully meet all the requirements of the application process to ensure that they are properly qualified to be an ONC–ATCB. We believe that our proposed process provides for a thorough and expeditious review of an application, which is in the best interest of all parties. We also believe that reviewing applications in two parts is the most efficient method, offers the most flexibility, and provides an applicant with the best opportunity to be successful. We do believe, however, that making some modifications to the application review process in response to comments will benefit both the applicants and the National Coordinator.

We agree with the commenter that additional clarity can be provided by specifically stating that the National Coordinator will review each part of the application in its entirety. Therefore, we have modified § 170.430(a)(2) to emphasize this point. We also can confirm that an applicant will have its initial Part 1 application reviewed and then have an opportunity to submit a revised application if necessary. Part 2 of an applicant's application will be given these same two opportunities for review only if Part 1 of the application is deemed satisfactory.

We agree with the commenter that the process for the National Coordinator to seek corrections of errors and omissions should be revised. Therefore, as recommended by the commenter, we are removing the words "inadvertent" and "minor" from § 170.430(b)(1). Although we anticipate that the National Coordinator would likely only seek correction of minor errors or omissions, these revisions provide the National Coordinator with more flexibility to allow an error or omission to be corrected instead of issuing a deficiency notice. This flexibility will be beneficial for both applicants and the National Coordinator considering the limited opportunities and short timeframes for correcting applications. In an effort to further increase the flexibility of the process, we are making additional revisions to § 170.430 in response to a commenter's recommendation. The commenter recommended that the National Coordinator should have the discretion, upon a showing of good cause by the applicant, to grant an extension beyond 15 days for an applicant to submit a revised application in response to a deficiency notice.

We agree with the commenter's recommendation and are revising § 170.430 to allow an applicant for ONC–ATCB status to request an extension of the 15-day period to submit a revised application in response to a deficiency notice and to provide the National Coordinator with the option of granting an applicant's request for additional time to respond to a deficiency notice upon a showing of good cause by the applicant. In determining whether good cause exists, the National Coordinator will consider factors such as: change in ownership or control of the applicant organization; the unexpected loss of a key member of the applicant's personnel; damage to or loss of use of the applicant's facilities, working environment or other resources; or other relevant factors that would prevent the applicant from submitting a timely response to a deficiency notice.

We believe it is unnecessary to establish a predetermined length of time for a good cause extension in the regulation text. The length of time for an extension will be based on an applicant's particular circumstances that constitute good cause for an extension. For example, if an applicant lost a key member of its personnel, then the timeframe extension would reflect a reasonable period of time in which the applicant could remedy that particular issue.

We believe that another means of adding greater flexibility to the application review process as sought by the commenter is to provide the National Coordinator with the same ability to request clarification of statements and the correction of errors or omissions in a revised application as the National Coordinator can do prior to issuing a deficiency notice. Accordingly, we are revising § 170.430 to state that the National Coordinator may request clarification of statements and the correction of errors or omissions during the 15-day period provided for review of a revised application.

2. ONC–ATCB Application Reconsideration

We proposed in section 170.435 that an applicant may request that the National Coordinator reconsider a denial notice issued for each part of an application only if the applicant can demonstrate that a clear, factual error(s) was made in the review of the application part and that the error's correction could lead to the applicant obtaining ONC–ATCB status. We proposed that the National Coordinator would have up to 15 days to consider a timely reconsideration request. We further proposed that if, after reviewing an applicant's reconsideration request, the National Coordinator determined that the applicant did not identify any factual errors or that correction of those factual errors would not remove all identified deficiencies in the application, the National Coordinator could reject the applicant's reconsideration request and that this decision would be final and not subject to further review.

In association with these proposals, we specifically requested that the public comment on whether there are instances, besides an applicant demonstrating that a clear, factual error was made in the review of its application and that the error's correction could lead to the applicant receiving ONC–ATCB status, in which the National Coordinator should reconsider an application that has been deemed deficient multiple times.

Comments. A commenter expressed agreement with our proposed ONC–ATCB application reconsideration process. Another commenter stated, however, that the National Coordinator should have discretion to reconsider an application that has been deemed deficient multiple times for reasons besides a clear factual error that could lead to the applicant receiving ONC–ATCB status. The commenter concluded that the National Coordinator is in the unique position to determine on a case-by-case basis whether multiple deficiencies should prevent reconsideration of a particular application. The commenter suggested that the National Coordinator should consider several factors in determining whether to reconsider an application that has been deemed deficient multiple times, including the severity and type of the deficiency, the implications of the deficiencies, the applicant's level of responsiveness and cooperation, and the remedial efforts taken by the applicant. The commenter also requested that, due to the differences between the proposed temporary and permanent certification programs and the timeframes associated with each, we consider applications for each program independently (*i.e.,* a reconsideration denial of an application under the temporary certification program would not impact an applicant's ability to apply to be an ONC–ACB under the permanent certification program).

Response. We appreciate the one commenter's expression of support for our proposals. We do not agree with the commenter that the National Coordinator should reconsider all twice-

deficient applications for any reason. Rather, we continue to believe that the National Coordinator should only reconsider an application if the applicant for ONC–ATCB status can demonstrate that there was a clear factual error in the review of its application that could lead to the applicant obtaining ONC–ATCB status. We believe that the application requirements and application review processes that we have proposed ensure that only qualified applicants are timely authorized to be ONC–ATCBs. The application requirements proposed are designed to ensure that applicants are qualified to both test and certify Complete EHRs and/or EHR Modules. Our review process is designed to establish the veracity of an application and to test and verify that an applicant has the necessary capabilities to be authorized to conduct the testing and certification sought by the applicant. Our review process is also designed to reach final decisions in a manner that will allow the temporary certification program to become operational in a timely manner. We believe the application review process contains sufficient opportunities for an applicant to demonstrate that it is qualified to be an ONC–ATCB, including opportunities under both Parts 1 and 2 of an application for the National Coordinator to request clarifications and corrections to the application, opportunities for an applicant to respond to a deficiency notice, and opportunities to request reconsideration of a denial notice if there is a clear, factual error that, if corrected, could lead to the applicant obtaining ONC–ATCB status. Accordingly, we have finalized this provision without modification.

We do, however, want to assure the commenter that a negative reconsideration decision regarding an application under the temporary certification program will not impact an applicant's ability to apply to be an ONC–ACB under the permanent certification program.

3. ONC–ATCB Status

We proposed in section 170.440 that the National Coordinator will acknowledge and make publicly available the names of ONC–ATCBs, including the date each was authorized and the type(s) of testing and certification each has been authorized to perform. We proposed that each ONC–ATCB would be required to prominently and unambiguously identify on its Web site and in all marketing and communications statements (written and oral) the scope of its authorization. We also proposed that an ONC–ATCB would not need to renew its status during the temporary certification program, but that an ONC–ATCB's status would expire upon the sunset of the temporary certification program in accordance with § 170.490.

Comments. A commenter expressed support for our proposal that an ONC–ATCB may only test and certify HIT that it is authorized to test and certify. Another commenter expressed an opinion that is important to the industry that the National Coordinator makes distinctions as to what a certifying body is approved to certify. One commenter recommended that our requirements related to marketing and communications be limited to the ONC–ATCB's Web site and all marketing and communications pertaining to its role in the testing and certification of EHRs and HIT. As currently written, the commenter contended that the requirements apply to all marketing and communications made by the entity even if unrelated to their ONC–ATCB status.

A commenter recommended that the authorization status of ONC–ATCBs should be limited to Stage 1 certification. Based on this recommendation, the commenter stated that the authorization should remain valid as long as Stage I incentives are available (*i.e.,* through 2014) and not expire upon the proposed sunset of the temporary certification program.

Response. We appreciate the support for our proposals and reiterate that, as proposed, an ONC–ATCB will only be able to test and certify Complete EHRs and/or EHR Modules consistent with the scope of authorization granted by the National Coordinator. Additionally, as proposed, the ONC–ATCB will have to prominently and unambiguously display the scope of authorization granted to it by the National Coordinator. To address the commenter's concern about the overreach of our proposed requirement that an ONC–ATCB "identify on its Web site and in all marketing and communications statements (written and oral) the scope of its authorization" we have clarified the language to clearly state that the requirement only applies to activities conducted by the ONC–ATCB under the temporary certification program. Specifically, we have revised the provision to state, in relevant part, "each ONC–ATCB must prominently and unambiguously identify the scope of its authorization on its Web site, and in all marketing and communications statements (written and oral) pertaining to its activities under the temporary certification program."

We do not accept the commenter's recommendation to associate authorization and the expiration of authorization to the stages of meaningful uses. As previously noted, the temporary certification program will sunset on December 31, 2011, or if the permanent certification program is not fully constituted at that time, then upon a subsequent date that is determined to be appropriate by the National Coordinator. Therefore, the temporary certification program must be capable of conducting testing and certification for the applicable stage(s) of meaningful use.

G. Testing and Certification of Complete EHRs and EHR Modules

We proposed in the Proposed Rule the scope of authority granted to ONC–ATCBs by ONC authorization. We also specified which certification criteria or certification criterion ONC–ATCBs would be required to use to test and certify Complete EHRs and EHR Modules.

1. Complete EHRs

We proposed in section 170.445 that to be authorized to test and certify Complete EHRs under the temporary certification program, an ONC–ATCB would need to be capable of testing and certifying Complete EHRs to all applicable certification criteria adopted by the Secretary at subpart C of part 170. We further proposed that an ONC–ATCB that had been authorized to test and certify Complete EHRs would also be authorized to test and certify all EHR Modules under the temporary certification program.

Comments. Commenters expressed agreement with our proposals that, in order to be authorized to test and certify Complete EHRs under the temporary certification program, an ONC–ATCB must be capable of testing and certifying Complete EHRs to all applicable certification criteria and that such an ONC–ATCB would also be authorized to test and certify all EHR Modules under the temporary certification program. One commenter recommended that we *require* ONC–ATCBs authorized to test and certify Complete EHRs to also test and certify EHR Modules.

Response. We appreciate the commenters' support for our proposals, but we do not adopt the one commenter's recommendation that we require an ONC–ATCB that is authorized to test and certify Complete EHRs to also test and certify EHR Modules. We clearly acknowledged in the preamble of the Proposed Rule and in our proposed regulatory provision that an ONC–ATCB authorized to test

and certify Complete EHRs would also have the capability and, more importantly, the authorization from the National Coordinator to test and certify EHR Modules. We do not, however, believe that we should regulate a private entity's business practices to require it to test and certify EHR Modules. An ONC–ATCB, despite authorization to do so, might have multiple business justifications for not testing and certifying EHR Modules, such as an insufficient number of qualified employees to conduct the testing and certification of EHR Modules in addition to conducting testing and certification of Complete EHRs, or that doing both would not be as profitable a business model.

Based on consideration of the comments received and review of the proposed provision, we are revising § 170.445(a) to state that "An ONC–ATCB must test and certify Complete EHRs to all applicable certification criteria adopted by the Secretary at subpart C of this part." This revision is consistent with our description of testing and certification of Complete EHRs in the Proposed Rule preamble. It also makes explicit that ONC–ATCBs must not only be capable, but as with EHR Modules, are required to test and certify Complete EHRs to the applicable certification criteria adopted by the Secretary under subpart C of Part 170.

2. EHR Modules

a. Applicable Certification Criteria or Criterion

We proposed in sections 170.450(a) and (b) that an ONC–ATCB must test and certify EHR Modules in accordance with the applicable certification criterion or criteria adopted by the Secretary at subpart C of part 170. In the preamble of the Proposed Rule, we clarified that a single certification criterion would encompass all of the specific capabilities referenced below the first paragraph level. For example, 45 CFR 170.302, paragraph "(e)" (the first paragraph level) identifies that this certification criterion relates to recording and charting vital signs. It includes three specific capabilities at (e)(1), (2), and (3) (the second paragraph level): The ability to record, modify, and retrieve patients' vital signs; the ability to calculate body mass index (BMI); and the ability to plot and display growth charts. We stated that we viewed the entire set of specific capabilities required by paragraph "(e)" (namely, (e)(1), (2), and (3)) as one certification criterion. The specific capability to calculate BMI, for example, would not be equivalent to one certification criterion.

Comments. We received two comments on our proposal. One commenter expressed agreement with our proposal, including the appropriateness of requiring an EHR Module to be capable of performing all the functions specified at the paragraph level of a certification criterion. The commenter reasoned that to allow testing and certification at a lower level (subparagraph) would result in a very large number of modules that would overcomplicate the certification program. The commenter stated that the only exception might be if there were a very large number of subparagraphs within a criterion or a very large number of criterion within a single objective (*e.g.,* if the number of quality measures remains very high). In that case, the commenter asserted that the module might be divided into two or more logically related groups. But in general, the commenter stated that having a range of 20–25 certification criteria, and therefore potential EHR Modules, was an appropriate level of granularity.

The other commenter stated that requiring a module to perform all of the listed functions or capabilities associated with a specific certification criterion would create a significant problem. In particular, the commenter stated that for the "drug-drug, drug-allergy, drug-formulary checks" certification criterion, there did not appear to be a single EHR Module in the current HIT marketplace that performs all of the four listed capabilities under the criterion. The commenter also surmised that the "incorporate clinical lab-test results into EHR as structured data" certification criterion may cause similar problems due to its multiple capabilities. Based on these considerations, the commenter recommended that we narrow the scope of EHR Module testing and certification to one of the capabilities or functions (subparagraphs) of a criterion. The commenter stated that this solution would necessitate that the ONC–ATCB provide modules that only perform such discrete functions with a "conditional certification" that carries the caveat that the module must be used in conjunction with other certified modules to offer full and complete functionality for the applicable criterion.

Response. We agree with the first commenter that, as proposed, EHR Modules should be tested and certified to the first paragraph level of a certification criterion, as described in the example above. We believe that this is the most appropriate level for testing and certification of EHR Modules because, in most cases, this level of a criterion most fully represents the capabilities that are needed to perform the associated meaningful use objectives.

We believe that the specific concerns raised by the commenter related to the "drug-drug, drug-allergy, drug-formulary checks" criterion and the "incorporate clinical lab-test results into EHR as structured data" criterion are more appropriately suited for discussion and resolution in the forthcoming final rule to finalize the certification criteria adopted in the HIT Standards and Certification Criteria interim final rule.

We are finalizing paragraph (a) of § 170.450 without modification, but we are modifying § 170.450 to remove paragraph (b) because it is repetitive of the requirements set forth in paragraph (a).

b. Privacy and Security Testing and Certification

With respect to EHR Modules, we discussed in the Proposed Rule when ONC–ATCBs would be required to test and certify EHR modules to the privacy and security certification criteria adopted by the Secretary. We proposed that EHR Modules must be tested and certified to all privacy and security certification criteria adopted by the Secretary unless the EHR Module(s) is/are presented for testing and certification in one of the following manners:

- The EHR Module(s) are presented for testing and certification as a pre-coordinated, integrated "bundle" of EHR Modules, which could otherwise constitute a Complete EHR. In such instances, the EHR Module(s) shall be tested and certified in the same manner as a Complete EHR. Pre-coordinated bundles of EHR Module(s) which include EHR Module(s) that would not be part of a local system and under the end user's direct control are excluded from this exception. The constituent EHR Modules of such an integrated bundle must be separately tested and certified to all privacy and security certification criteria;
- An EHR Module is presented for testing and certification, and the presenter can demonstrate to the ONC–ATCB that it would be technically infeasible for the EHR Module to be tested and certified in accordance with some or all of the privacy and security certification criteria; or
- An EHR Module is presented for testing and certification, and the presenter can demonstrate to the ONC–ATCB that the EHR Module is designed to perform a specific privacy and security capability. In such instances,

the EHR Module may only be tested and certified in accordance with the applicable privacy and security certification criterion/criteria.

Comments. A number of commenters supported our proposed approach and agreed that EHR Modules should be tested and certified to all adopted privacy and security certification criteria unless there were justifiable reasons for which they should not. Other commenters suggested changes to one or more of the stated exceptions and posed questions for our consideration. Some commenters recommended that we deem certification criteria "addressable" similar to the Health Insurance Portability and Accountability Act (HIPAA) Security Rule's application of the word "addressable" to certain implementation specifications (in the HIPAA context) within a security standard (in the HIPAA context). Other commenters noted that with respect to the second exception, involving the demonstration that it would be technically infeasible for an EHR Module to be tested and certified to some or all privacy and security certification criteria, that the term "inapplicable" should be added as a condition in addition to "technically infeasible." Another commenter stated that we should remove the third exception, involving the demonstration that an EHR Module is designed to perform a specific privacy and security capability, because, depending on how the privacy and security EHR Module is developed, it may also need to include certain capabilities, such as an audit log.

Response. We appreciate commenters' support for our proposed approach and the thoughtfulness of the responses. While we understand and appreciate the similarities some commenters saw with respect to the HIPAA Security Rule and leveraging the "addressable" concept, we do not believe that making each privacy and security certification criterion "addressable" in the way it is implemented under the HIPAA Security Rule is an appropriate approach for the purposes of testing and certifying EHR Modules.

In the context of the HIPAA Security Rule, HIPAA covered entities must assess whether each addressable implementation specification (in the HIPAA Security Rule) is a reasonable and appropriate safeguard in its environment. If a HIPAA covered entity determines that an addressable implementation specification is reasonable and appropriate, then the covered entity is required to implement it. If a HIPAA covered entity determines that an addressable implementation specification is not reasonable and appropriate, the covered entity is required to: (1) document why it would not be reasonable and appropriate to implement the addressable implementation specification; and (2) implement an equivalent alternative measure if reasonable and appropriate. While this is a sensible approach for HIPAA covered entities, we do not believe that it translates well into the testing and certification of EHR Modules.

All HIPAA covered entities are required to comply with the HIPAA Security Rule with respect to their electronic protected health information, regardless of their size and resources. Accordingly, the HIPAA Security Rule provides for a flexible approach, allowing a HIPAA covered entity to implement safeguards that are reasonable and appropriate for its unique environment. We do not believe that this approach is appropriate for testing and certifying EHR Modules because one purpose of certification is to assure eligible professionals and eligible hospitals that an EHR Module includes a specified capability or set of capabilities. For these reasons, we believe that the proposed standard of "technically infeasible" is more appropriate than the HIPAA Security Rule's "addressable" concept for the purposes of testing and certifying EHR Modules. Thus, an EHR Module developer must satisfy each privacy and security criterion where it is technically feasible.

To complement our "technically infeasible" standard, we agree with those commenters that recommended the addition of the word "inapplicable" to the second proposed exception. We believe that in some cases a privacy and security certification criterion may be inapplicable to an EHR Module while technically feasible to implement, and in other cases a privacy and security certification criterion may be applicable but technically infeasible to implement. For example, it may be technically feasible to implement an automatic log-off or emergency access capability for several types of EHR Modules, but such capabilities may be inapplicable given the EHR Module's anticipated function and/or point of integration.

We require that an EHR Module developer provide sufficient documentation to support a claim that a particular privacy and security certification criterion is inapplicable or that satisfying the certification criterion is technically infeasible. Based on this documentation, the ONC–ATCB should independently assess and make a reasonable determination as to whether the EHR Module should be exempt from having to include a particular privacy or security capability.

We also agree with the commenter that stated that we should remove the third exception and simply require all modules, if not included in a pre-coordinated integrated bundle, to follow the same approach. As a result, only the first and second exception will be included in the final rule. We recognize that, with respect to an EHR Module that is focused exclusively on providing one or more privacy and security capabilities, the remaining privacy and security certification criteria may be inapplicable or compliance with them may be technically infeasible. However, we do not believe it is prudent to presume that this will always be the case.

Comments. Several commenters asked for clarification on the circumstances under which the first exception we proposed applied in relation to a pre-coordinated, integrated "bundle" of EHR Modules, the carve out to this exception related to EHR Modules that were "not be part of a local system," and our use of the term "end user."

Response. Overall, the premise behind the first exception is to release the general requirement that each individual EHR Module be tested and certified to all adopted privacy and security criteria. We believe that it would be pragmatic to release this requirement in situations where several EHR Module developers (*e.g.,* different vendors) or a single EHR Module developer presents a collection of EHR Modules as a pre-coordinated, integrated bundle to an ONC–ATCB for testing and certification. In these circumstances, the integrated bundle of EHR Modules would otherwise constitute a Complete EHR. Therefore, we clarify that in the circumstances where an integrated bundle of EHR Modules is presented for testing and certification and one or more of the constituent EHR Modules is/are demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules, that those other EHR Modules would be exempt from being tested and certified to adopted privacy and security certification criteria. To illustrate, four EHR Module developers each develop one EHR Module (EHR Modules A, B, C, and D) and form an affiliation. The EHR Module developers present their EHR Modules for testing and certification as an integrated bundle and identify that EHR Module "C" is responsible for providing the privacy and security capabilities for the rest of the entire bundle (EHR Modules A, B, and D). In this scenario, EHR Modules A, B, and D

would be exempt from also being tested and certified to the adopted privacy and security certification criteria.

With respect to the proposed carve out to this exception related to EHR Modules that were "not be part of a local system," we sought to limit those circumstances where a group of EHR Module developers could claim that a collection of EHR Modules was an "integrated bundle," yet it would be technically infeasible for one or all of the EHR Modules in the collection to be demonstrably responsible for providing all of the privacy and security capabilities for the rest of the EHR Modules. We believe this would occur in situations where a presented "integrated bundle" of EHR Modules includes one or more services offered by different EHR Module developers that have been implemented on different technical architectures or hosted over the Internet on one or multiple different servers. In this situation we do not believe that it would be possible for one or more of the EHR Modules to be demonstrably responsible for providing all of the privacy and security capabilities for the rest of the EHR Modules. For example, we do not believe that it is possible, at the present time, for a web-based EHR Module to offer authentication for another EHR Module that may be installed on an eligible professional's laptop, nor do we believe that one or more web-based services could provide an audit log for actions that took place outside of that service.

We believe that with this additional clarity the explicit mention of the first exception's carve out is no longer necessary and have revised the first exception accordingly to include the clarifying concepts we discuss above. This revision has also resulted in the removal of the term "end user," which commenters requested we clarify. The entire provision, including the changes from both our responses above, will read:

EHR Modules shall be tested and certified to all privacy and security certification criteria adopted by the Secretary unless the EHR Module(s) is/are presented for testing and certification in one of the following manners:

(1) The EHR Module(s) is/are presented for testing and certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR (as defined in 45 CFR 170.102), and one or more of the constituent EHR Modules is/are demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Module(s); or

(2) An EHR Module is presented for testing and certification, and the presenter can demonstrate to the ONC–ATCB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be tested and certified in accordance with such certification criterion.

We would like to clarify two points related to integrated bundles of EHR Modules. First, an integrated bundle of EHR Modules will only qualify for this special treatment if, and only if, the integrated bundle would otherwise constitute a Complete EHR. In other words, three EHR Modules that have been integrated and "bundled" but do not meet the definition of Complete EHR, would not qualify for this specific certification. In those cases, we would view such a bundle as an EHR Module that provides multiple capabilities. Second, because an integrated bundle of EHR Modules would otherwise constitute a Complete EHR, we would treat it as a Complete EHR and when listing it as part of our master certified HIT products list, we would provide a designation, noting that it was an integrated bundle of EHR Modules.

Comments. A few commenters requested that we clarify whether there could be specific privacy and security-focused EHR Modules. That is, in the context of the definition of EHR Module, whether we intended to permit EHR Modules to exist that only addressed one or more adopted privacy and security certification criteria. One commenter asked for clarification as to whether a specific privacy and security-focused EHR Module would meet a certification criterion if its purpose was to call or assign the actual capability required by a certification criterion to another function or service.

Response. Yes, we believe that there could be specific privacy and security-focused EHR Modules and do not preclude such EHR Modules from being presented for certification. However, with respect to the second comment and request for clarification, we believe that an EHR Module, itself, must be capable of performing a capability required by an adopted privacy and security certification criterion and that delegating the responsibility to another service or function would not be acceptable. In those cases there would be no proof that the EHR Module could actually perform the specific capability, only that it could tell something else to do it.

c. Identification of Certified Status

We proposed in section 170.450(d) to require ONC–ATCBs authorized to test and certify EHR Modules to clearly indicate the certification criterion or criteria to which an EHR Module has been tested and certified in the EHR Module's certification documentation.

Comments. We received two comments requesting that we standardize the certification documentation requirements or at least provide clear guidelines for certificate design. The commenters were concerned that if left to the discretion of ONC–ATCBs, the resulting certification certificates could look quite different and result in marketplace confusion. One commenter recommended that the certification certificate, which will figure prominently in EHR software vendor marketing, should be uniform in appearance and depict HHS authority and assurance.

Response. We agree with the commenters that certificate documentation should be designed in a way that does not lead to market confusion. Therefore, we are establishing a new Principle of Proper Conduct for ONC–ATCBs regarding the proper identification of Complete EHRs and EHR Modules. We further discuss the basis for this new Principle of Proper Conduct under the heading titled "*O. Validity of Complete EHR and EHR Module Certification and Expiration of Certified Status*" later in this section. Consistent with this decision, we are modifying proposed § 170.450 to remove paragraph (d). This modification will eliminate any potential redundancy with the new Principle of Proper Conduct on the proper identification of Complete EHRs and EHR Modules.

H. The Testing and Certification of "Minimum Standards"

In the Proposed Rule, we summarized the approach set forth in the HIT Standards and Certification Criteria interim final rule (75 FR 2014) to treat certain vocabulary code set standards as "minimum standards." We noted that the establishment of "minimum standards" for specific adopted code sets would, in certain circumstances, allow a Complete EHR and/or EHR Module to be tested and certified to a permitted newer version of an adopted code set without the need for additional rulemaking. Additionally, we noted that this approach would enable Certified EHR Technology to be upgraded to a permitted newer version of a code set without adversely affecting its certified status.

At the end of this summary, we reiterated a previously identified limitation of the "minimum standards" approach with respect to significant revisions to adopted code sets. We stated that a newer version of an adopted "minimum standard" code set would be permitted for use in testing and certification unless it was a significant revision to a code set that represented a "modification, rather than maintenance or a minor update of the code set." In those cases, we reiterated that the Secretary would likely proceed with notice and comment rulemaking to adopt a significantly revised code set standard.

We proposed two methods through which the Secretary could identify new versions of adopted "minimum standard" code sets. The first method would allow any member of the general public to notify the National Coordinator about a new version. Under the second method, the Secretary would proactively identify newly published versions. After a new version has been identified, a determination would be issued as to whether the new version constitutes maintenance efforts or minor updates of the adopted code set and consequently would be permitted for use in testing and certification. We further proposed that once the Secretary has accepted a new version of an adopted "minimum standard" code set that:

(1) Any ONC–ATCB may test and certify Complete EHRs and/or EHR Modules according to the new version;

(2) Certified EHR Technology may be upgraded to comply with the new version of an adopted minimum standard accepted by the Secretary without adversely affecting the certification status of the Certified EHR Technology; and

(3) ONC–ATCBs would not be required to test and certify Complete EHRs and/or EHR Modules according to the new version until we updated the incorporation by reference of the adopted version to a newer version.

Finally, we stated that for either method, we would regularly publish on a quarterly basis, either by presenting to the HIT Standards Committee or by posting a notification on our Web site, any Secretarial determinations that have been made with respect to "minimum standard" code sets. We requested public comment on the frequency of publication, any other approaches we should consider to identify newer versions of adopted code set standards, and whether both methods described above should be used.

Comments. Many commenters supported our proposed approaches. These commenters also encouraged us to pursue both of the proposed approaches (notification of the National Coordinator by the general public and proactive identification by the Secretary). Some commenters recommended that we establish open lines of communication with the organizations responsible for maintaining identified "minimum standard" code sets in order to facilitate the process of identifying newer versions.

Response. We appreciate the commenters' support for our proposals. Based on this feedback, we have decided to adopt both of the approaches we have proposed. In addition, we expect to work, as appropriate, with the maintenance organizations for the "minimum standard" code sets, as well as the HIT Standards Committee, to identify new versions when they become available.

Comments. A few commenters recommended that ONC–ATCBs not be required to use an accepted newer version of a "minimum standard" code set for certification. Along those lines, a few other commenters recommended that there be a delay period between the Secretary's acceptance of a new version and when it would be required for testing and certification. One commenter noted that supporting multiple versions of standards should be avoided and that there would be differences in what was certified versus what was implemented, while another noted that even permitting the use of a minor update could affect interoperability. Some commenters specifically requested clarification regarding the timeline associated with the Secretary's acceptance of a newer version and its publication and what requirement there would be for its inclusion in testing and certification.

Response. We believe that some commenters misunderstood the implications of the Secretary's acceptance of a newer version of a "minimum standard" code set. We therefore clarify that if the Secretary accepts a newer version of a "minimum standard" code set, *nothing is required* of ONC–ATCBs, Complete EHR or EHR Module developers, or the eligible professionals and eligible hospitals who have implemented Certified EHR Technology. In the Proposed Rule, we used a three-pronged approach in order to provide greater flexibility and accommodate industry practice with respect to code sets that must be maintained and frequently updated. The first prong would permit, but *not require,* ONC–ATCBs to use an accepted newer version of a "minimum standard" code set to test and certify Complete EHRs and/or EHR Modules if the accepted newer version has been incorporated into a product by a Complete EHR or EHR Module developer. In these instances, we believe this approach benefits Complete EHR or EHR Module developers because they would be able to adopt a newer version of a code set voluntarily and have their Complete EHR or EHR Module certified according to it, rather than having to use an older version for certification. The second prong would permit, but *not require,* eligible professionals and eligible hospitals who are already using Certified EHR Technology to receive an upgrade from their Complete EHR or EHR Module developer or voluntarily upgrade themselves to an accepted newer version of a "minimum standard" code set without adversely affecting the certification status of their Certified EHR Technology. Again, we believe this is a benefit to eligible professionals and eligible hospitals and provides greater flexibility. The third prong explicitly states that an ONC–ATCB would not be required to use any other version of a "minimum standard" code set beyond the one adopted at 45 CFR part 170 subpart B until the Secretary incorporates by reference a newer version of that code set.

We recognize that a few different versions of adopted "minimum standards" could all be implemented at the same time and before a subsequent rulemaking potentially changes what constitutes the "minimum." We also understand the point raised by the commenter who expressed concerns about this approach because it could potentially create a situation where there could be differences in what was certified versus what was implemented. Along those lines, we also appreciate the point made by the commenter that a minor update could affect interoperability. We acknowledge these concerns and considered them as part of our analysis in determining whether to adopt minimum standards and to permit such standards to be exceeded when newer versions had been made available for use. However, we would like to make clear that we provide this flexibility on a voluntary basis and believe that the benefit of accepting newer versions of a "minimum standard" (namely, enabling the HIT industry to keep pace with new code sets) outweighs any potential or temporary risk to interoperability.

In light of the discussion above, we do not believe it is necessary to change any of our proposals, and we hope the additional clarification above addresses

the concerns and questions raised by commenters.

Comments. Some commenters requested that we clarify the process the Secretary would follow before accepting a newer version of an adopted "minimum standard" code set.

Response. We expect that after a new version of an adopted "minimum standard" code set has been identified (either through the general public's notification of the National Coordinator or the Secretary proactively identifying its availability), the National Coordinator would ask the HIT Standards Committee to assess and solicit public comment on the new version. We expect that the HIT Standards Committee would subsequently issue a recommendation to the National Coordinator which would identify whether the Secretary's acceptance of the newer version for voluntary implementation and testing and certification would burden the HIT industry, negatively affect interoperability, or cause some other type of unintended consequence. After considering the recommendation of the HIT Standards Committee, the National Coordinator would determine whether or not to seek the Secretary's acceptance of the new version of the adopted "minimum standard" code set. If the Secretary approves the National Coordinator's request, we would issue guidance on an appropriate but timely basis indicating that the new version of the adopted "minimum standard" code set has been accepted by the Secretary.

I. Authorized Testing and Certification Methods

We proposed in section 170.457 that, as a primary method, an ONC–ATCB would be required to be capable of testing and certifying Complete EHRs and/or EHR Modules at its facility. We also proposed that an ONC–ATCB would be required to have the capacity to test and certify Complete EHRs and/or EHR Modules through one of the following secondary methods: at the site where the Complete EHR or EHR Module has been developed; or at the site where the Complete EHR or EHR Module resides; or remotely (*i.e.,* through other means, such as through secure electronic transmissions and automated web-based tools, or at a location other than the ONC–ATCB's facilities).

Comments. We received many comments on our proposal. We received varying recommendations and proposals, but the majority of commenters did not agree with testing and certification at an ONC–ATCB's facility as the primary method. Commenters noted that to require eligible professionals or eligible hospitals with self-developed Complete EHRs to physically move their Complete EHRs to another location for testing and certification would not only be burdensome but in many cases impossible. Instead, many commenters recommended that we require ONC–ATCBs to have the capacity to certify products through all of the secondary methods we proposed. Some commenters supported secondary methods without preference, while many commenters recommended that we require ONC–ATCBs to offer remote testing as the primary method because of its efficiency and low cost to Complete EHR and EHR Module developers. Commenters also noted that ONC–ATCBs could offer other methods, including performing testing and certification at an ONC–ATCB's facility. One commenter recommended that, as the primary method, ONC–ATCBs should be required to support testing and certification at the Complete EHR or EHR Module developer's site, which could include a development or deployment site. Another commenter stated that each method should be considered equal because different methods may be appropriate for different developers. Some commenters recommended that we clarify whether we expected Complete EHRs and EHR Modules to be "live" at customer sites before they can be tested and certified. The commenters asserted that such a prerequisite will significantly delay the roll out of customer upgrades.

Response. We appreciate the many options and preferences expressed by the commenters. We believe that in order to adequately and appropriately address the commenters' concerns, an ONC–ATCB must have the capacity to provide remote testing and certification for both development and deployment sites. A development site is the physical location where a Complete EHR or EHR Module was developed. A deployment site is the physical location where a Complete EHR or EHR Module resides or is being or has been implemented. As discussed in the Proposed Rule, remote testing and certification would include the use of methods that do not require the ONC–ATCB to be physically present at the development or deployment site. This could include the use of web-based tools or secured electronic transmissions. In addition to remote testing and certification, an ONC–ATCB may also offer testing and certification at its facility or at the physical location of a development or deployment site, but we are not requiring that an ONC–ATCB offer such testing and certification. As indicated by commenters and our own additional research, the market currently utilizes predominantly remote methods for the testing and certification of HIT. On-site testing and certification was cited as costly and inefficient. Therefore, we are not requiring ONC–ATCBs to offer such testing and certification, but anticipate that some ONC–ATCBs will offer on-site testing and certification if there is a market demand. In response to those commenters who requested clarification, we also want to make clear that we do not believe that a Complete EHR or EHR Module must be "live at a customer's site" in order to qualify for testing and certification by an ONC–ATCB. As stated above, a Complete EHR or EHR Module could be tested and certified at a Complete EHR and/or EHR Module developer's development site. Consistent with this discussion, we have revised § 170.457 to require an ONC–ATCB to provide remote testing and certification for both development and deployment sites and have included the definitions of "development site," "deployment site," and "remote testing and certification" in § 170.402.

J. Good Standing as an ONC–ATCB, Revocation of ONC–ATCB Status, and Effect of Revocation on Certifications Issued by a Former ONC–ATCB

We proposed in the Proposed Rule requirements that ONC–ATCBs would need to meet in order to maintain good standing under the temporary certification program, the processes for revoking an ONC–ATCB's status for failure to remain in good standing, the effects that revocation would have on a former ONC–ATCB, and the potential effects that revocation could have on certifications issued by the former ONC–ATCB.

1. Good Standing as an ONC–ATCB

We proposed in section 170.460 that, in order to maintain good standing, an ONC–ATCB would be required to adhere to the Principles of Proper Conduct for ONC–ATCBs and refrain from engaging in other types of inappropriate behavior, such as misrepresenting the scope of its authorization or testing and certifying Complete EHRs and/or EHR Modules for which it was not given authorization. In order to maintain good standing, we also proposed that an ONC–ATCB would be expected to follow all applicable Federal and state laws.

Comments. Commenters expressed opinions that ONC–ATCBs should be expected to meet high standards for ethics and compliance, and therefore

were appreciative of our proposed standards of conduct for ONC–ATCBs. One commenter encouraged us to evaluate ONC–ATCBs' compliance with the Principles of Proper Conduct on an ongoing basis and at the time for re-authorization, particularly if either a Type-1 or Type-2 violation had occurred.

Response. We believe that our proposed Principles of Proper Conduct for ONC–ATCBs are essential to maintaining the integrity of the temporary certification program, as well as ensuring public confidence in the program and the Complete EHRs and EHR Modules that are tested and certified under the program. We intend to monitor compliance with the Principles of Proper Conduct for ONC–ATCBs on an ongoing basis by, among other means, following up on concerns expressed by Complete EHR and EHR Module developers and the general public. It is also expected that ONC–ATCBs will maintain relevant documentation of their compliance with the Principles of Proper Conduct for ONC–ATCBs because such documentation would be necessary, for instance, to rebut a notice of noncompliance with the Principles of Proper Conduct issued by the National Coordinator. We continue to believe that a violation of the Principles of Proper Conduct for ONC–ATCBs, a violation of law, or other inappropriate behavior must be promptly and appropriately addressed to maintain the program's integrity and the public's confidence in the program and the products that are certified. If a violation or other inappropriate behavior were to occur, it would be addressed in accordance with section 170.465. With consideration of the public comments received, we are finalizing section 170.460 without modification.

2. Revocation of ONC–ATCB Status

We proposed in section 170.465 that the National Coordinator could revoke an ONC–ATCB's status if it committed a Type-1 violation or if it failed to timely or adequately correct a Type-2 violation. We defined Type-1 violations to include violations of law or temporary certification program policies that threaten or significantly undermine the integrity of the temporary certification program. These violations include, but are not limited to: false, fraudulent, or abusive activities that affect the temporary certification program, a program administered by HHS or any program administered by the Federal government.

We defined Type-2 violations as noncompliance with § 170.460, which would include without limitation, failure to adhere to the Principles of Proper Conduct for ONC–ATCBs and engaging in other inappropriate behavior. We proposed that if the National Coordinator were to obtain reliable evidence that an ONC–ATCB may no longer be in compliance with § 170.460, the National Coordinator would issue a noncompliance notification. We proposed that an ONC–ATCB would have an opportunity to respond and demonstrate that no violation occurred or that the alleged violation had been corrected. We further proposed that the National Coordinator would review the response and determine whether a violation had occurred and whether it had been adequately corrected.

We proposed that the National Coordinator could propose to revoke an ONC–ATCB's status if the National Coordinator has evidence that the ONC–ATCB committed a Type-1 violation. We proposed that the National Coordinator could propose to revoke an ONC–ATCB's status if the ONC–ATCB failed to rebut an alleged Type-2 violation with sufficient evidence showing that the violation did not occur or that the violation had been corrected, or if the ONC–ATCB did not submit a written response to a Type-2 noncompliance notification within the specified timeframe. We proposed that an ONC–ATCB would be able to continue its operations under the temporary certification program during the time periods provided for the ONC–ATCB to respond to a proposed revocation notice and the National Coordinator to review the response.

We proposed that the National Coordinator could revoke an ONC–ATCB's status if it is determined that revocation is appropriate after considering the ONC–ATCB's response to the proposed revocation notice or if the ONC–ATCB does not respond to a proposed revocation notice within the specified timeframe. We further proposed that a decision to revoke an ONC–ATCB's status would be final and not subject to further review unless the National Coordinator chose to reconsider the revocation.

We proposed that a revocation would be effective as soon as the ONC–ATCB received the revocation notice. We proposed that a testing and certification body that had its ONC–ATCB status revoked would be prohibited from accepting new requests for testing and certification and would be required to cease its current testing and certification operations under the temporary certification program. We further proposed that if a testing and certification body had its ONC–ATCB status revoked for a Type-1 violation, it would be prohibited from reapplying for ONC–ATCB status under the temporary certification program for one year. If the temporary certification program sunset during this time, the testing and certification body would be prohibited from applying for ONC–ACB status under the permanent certification program for the remainder of the one year prohibition period.

We proposed that failure to promptly refund any and all fees for uncompleted tests and/or certifications of Complete EHRs and EHR Modules after the revocation of ONC–ATCB status would be considered a violation of the Principles of Proper Conduct for ONC–ATCBs. We proposed that the National Coordinator would consider such violations in the event that a testing and certification body reapplied for ONC–ATCB status under the temporary certification program or applied for ONC–ACB status under the permanent certification program.

In association with these proposals, we specifically requested that the public comment on two additional proposals. First, we requested that the public comment on whether the National Coordinator should consider proposing the revocation of an ONC–ATCB's status for repeatedly committing Type-2 violations even if the ONC–ATCB adequately corrected the violations each time. In conjunction with this request, we asked how many corrected Type-2 violations would be sufficient for proposing revocation of an ONC–ATCB and to what extent the frequency of these violations should be a consideration. Second, we requested that the public comment on whether the National Coordinator should also include a process to suspend an ONC–ATCB's status.

Comments. We received general support for our proposed revocation process with commenters encouraging us to take a stringent position regarding Type-1 and Type-2 violations out of fear that a lack of confidence in the qualifications or integrity of an ONC–ATCB could seriously undermine the temporary certification program's objectives. Commenters requested that vendors, self-developers and providers be notified if an ONC–ATCB is suspended, the National Coordinator proposes to revoke an ONC–ATCB's status, and/or an ONC–ATCB's status is revoked. One commenter recommended that there not be a "broad" categorical Type-1 violation bar on reapplying for ONC–ATCBs that had their status revoked, while other commenters suggested that we extend the timeframe

for barring ONC–ATCBs that have committed Type-1 violations from reapplying to at least three years and to require that a "re-authorized" former ONC–ATCB serve a probationary period.

We received a few comments on whether we should revoke an ONC–ATCB's status under the temporary certification program for committing multiple Type-2 violations even if the violations were corrected. A couple of commenters suggested that an ONC–ATCB should have its status revoked for committing multiple violations. One commenter reasoned that if an ONC–ATCB committed three or more violations in the short time of the anticipated existence of the temporary certification program then it deserved to have its status revoked. Another commenter recommended that the National Coordinator retain the discretion to review and judge each situation as opposed to setting a certain threshold for automatic revocation.

We received multiple comments on our proposed alternative of a suspension process with all of the commenters suggesting that there could be value in a suspension process. One commenter stated that our goal should be first and foremost to protect the needs of product purchasers and patients. Commenters stated that suspension could be warranted in lieu of proposing revocation and/or during the period between a proposed revocation and a final decision on revocation. Some commenters recommended that an ONC–ATCB be allowed to continue operations during a suspension or be provided "due process" rights before being suspended, while others suggested that allowing an ONC–ATCB to continue during instances where an investigation is ongoing and violations are being resolved could jeopardize the industry's confidence level in the certification process. One commenter suggested that an ONC–ATCB be allowed to continue operations unless the alleged violation would or could adversely impact patient safety and/or quality of care.

Response. We do not believe that it is appropriate to initiate revocation proceedings against an ONC–ATCB for any amount of corrected Type-2 violations under the temporary certification program. We did not originally propose to initiate revocation proceedings for multiple corrected Type-2 violations, but requested public comment on the possibility. Commenters appeared to agree that initiating revocation proceedings against an ONC–ATCB for committing multiple Type-2 violations, even if corrected, was an acceptable proposition under certain conditions. While we agree that committing multiple Type-2 violations, even if corrected, is cause for concern, it would be difficult to establish a sufficiently objective and equitable standard for initiating revocation proceedings on that basis against an ONC–ATCB. As evidenced by the comments, it is difficult to determine the appropriate number of corrected Type-2 violations that would lead to revocation proceedings. An ONC–ATCB could commit and correct two Type-2 violations involving a missed training or a timely update to ONC on a key personnel change. In such a situation, we do not believe that automatically initiating revocation proceedings would be warranted. We also do not believe it would be appropriate to adopt the one commenter's recommendation to allow the National Coordinator to use discretion to address such instances. This would not give an ONC–ATCB sufficient notice of what Type-2 violation, even if corrected, could lead to revocation proceedings nor an indication of the amount or frequency of the violations that could lead to revocation proceedings. Therefore, we believe that an ONC–ATCB should remain in good standing if it sufficiently corrects a Type-2 violation, no matter how many times an ONC–ATCB commits a Type-2 violation. Such violations will be a matter of public record that may influence Complete EHR and EHR Module developers' decisions on which ONC–ATCB to select for the testing and certification of their Complete EHRs and/or EHR Modules.

We believe that Type-1 violations as described are not too "broad" in that they must also "threaten or significantly undermine the integrity of the temporary certification program." In such cases, we believe that barring a former ONC–ATCB from reapplying for ONC–ATCB status for one year is an appropriate remedy under the temporary certification program, which we do not anticipate lasting beyond December 31, 2011. As noted in the Proposed Rule, a Type-1 violation could significantly undermine the public's faith in our temporary certification program. Therefore, removing the ONC–ATCB from the program is an appropriate remedy. The 1-year bar on reapplying will allow the former ONC–ATCB sufficient time to address the reasons for the Type-1 violation before reapplying. We will, however, reconsider the appropriate length of a bar on reapplying for ONC–ACB status and whether a probationary period would be appropriate for the permanent certification program when we finalize the permanent certification program.

We agree with the commenters that suspension could be an effective way to protect purchasers of certified products and ensure patient health and safety. As a result, we agree with the commenter and believe that the National Coordinator should have the ability to suspend an ONC–ATCB's operations under the temporary certification program when there is reliable evidence indicating that the ONC–ATCB committed a Type-1 or Type-2 violation and that the continued testing and certification of Complete EHRs and/or EHR Modules could have an adverse impact on patient health or safety. As mentioned in the Proposed Rule, the National Coordinator's process for obtaining reliable evidence would involve one or more of the following methods: Fact-gathering; requesting information from an ONC–ATCB; contacting an ONC–ATCB's customers; witnessing an ONC–ATCB perform testing or certification; and/or reviewing substantiated complaints.

Due to the disruption a suspension may cause for an ONC–ATCB, and more so for the market, we believe that suspension is appropriate in only the limited circumstances described above and have revised § 170.465 to provide the National Coordinator with the discretion to suspend an ONC–ATCB's operations accordingly. An ONC–ATCB would first be issued a notice of proposed suspension. Upon receipt of a notice of proposed suspension, an ONC–ATCB will be permitted up to 3 days to submit a written response to the National Coordinator explaining why its operations should not be suspended. The National Coordinator will be permitted up to 5 days to review the ONC–ATCB's response and issue a determination. In the determination, the National Coordinator will either rescind the proposed suspension, suspend the ONC–ATCB's operations until it has adequately corrected a Type-2 violation, or propose revocation in accordance with § 170.465(c) and suspend the ONC–ATCB's operations for the duration of the revocation process. The National Coordinator may also make any one of the above determinations if an ONC–ATCB fails to submit a timely response to a notice of proposed suspension. A suspension will become effective upon an ONC–ATCB's receipt of a notice of suspension. We believe that this process addresses the commenters' concerns regarding due process and maintaining the industry's confidence in the temporary certification program by not allowing an

ONC–ATCB to continue operations while an investigation is ongoing and/or violations are being resolved related to the patient health or safety.

As discussed in a previous section of this preamble, we have revised § 170.423(j) to clarify that an ONC–ATCB would have to refund any fees paid by a Complete EHR or EHR Module developer that seeks to withdraw a request for testing and certification while an ONC–ATCB is suspended.

We intend to provide public notification via our Web site and list serve if an ONC–ATCB is suspended, issued a notice proposing its revocation, and/or has its status revoked. We also note that we revised § 170.465(c)(1) to state that "[t]he National Coordinator may propose to revoke an ONC–ATCB's status if the National Coordinator has reliable evidence that the ONC–ATCB committed a Type-1 violation." The term "reliable" was inadvertently left out of the Proposed Rule.

3. Effect of Revocation on Certifications Issued by a Former ONC–ATCB

We proposed in section 170.470 to allow the certified status of Complete EHRs and/or EHR Modules certified by an ONC–ATCB that subsequently had its status revoked to remain intact unless a Type-1 violation was committed that called into question the legitimacy of the certifications issued by the former ONC–ATCB. In such circumstances, we proposed that the National Coordinator would review the facts surrounding the revocation of the ONC–ATCB's status and publish a notice on ONC's Web site if the National Coordinator believed that Complete EHRs and/or EHR Modules were fraudulently certified by a former ONC–ATCB and the certification process itself failed to comply with regulatory requirements. We further proposed that if the National Coordinator determined that Complete EHRs and/or EHR Modules were improperly certified, the "certified status" of affected Complete EHRs and/or EHR Modules would remain intact for 120 days after the National Coordinator published the notice. We specifically requested that the public comment on our proposed approach and the timeframe for re-certification.

Comments. Multiple commenters expressed agreement and understanding with the need to protect the integrity of the temporary certification program by ensuring the legitimacy of certifications issued by a former ONC–ATCB and requiring recertification of Complete EHRs and/or EHR Modules where it is found that they were improperly certified. Many commenters stated, however, that we should determine whether an improperly certified product negatively and substantially affected the performance of a Complete EHR or EHR Module in achieving a meaningful use objective before requiring recertification. Other commenters stated that "good faith" eligible professionals and eligible hospitals who can demonstrate meaningful use with a previously certified Complete EHR or EHR Module should continue to qualify for payments under the Medicare and Medicaid EHR Incentive Programs. Commenters further stated that providers should be allowed to replace the previously certified product when new certification criteria have been finalized for the affected meaningful use criteria, or when their own strategic and technical requirements necessitate an upgrade, whichever comes first. Commenters contended that the only overriding factor that should require recertification is if there is a demonstrable risk to patient safety from the use of improperly certified Complete EHRs and/or EHR Modules.

A few commenters expressed concerns about the potential negative financial impact recertification would have on Complete EHR and EHR Module developers, eligible professionals and eligible hospitals as well as the potential for legal liability related to eligible professionals and eligible hospitals making attestations to federal and state agencies that they are using Certified EHR Technology.

Some commenters agreed with our 120-day proposal, while many commenters recommended 6, 9, 12, and 18-month "grace periods" for improperly certified Complete EHRs and/or EHR Modules. One commenter recommended an extension of the 120-day grace period if there were less than 3 ONC–ATCBs at the time of decertification. One commenter noted that the revocation process through potential decertification of Complete EHRs and/or EHR Modules could take longer than the life of the temporary certification program and likely overlap with the issuance of new standards and certification criteria, which itself will require "recertification" under the permanent certification program.

Response. In instances where the National Coordinator determines that Complete EHRs and/or EHR Modules were improperly certified, we believe that recertification is necessary to maintain the integrity of the temporary certification program and to ensure the efficacy and safety of certified Complete EHRs and EHR Modules. By requiring recertification, eligible professionals and eligible hospitals as well as Complete EHR and EHR Module developers can have confidence in the temporary certification program and, more importantly, in the Complete EHRs and EHR Modules that are certified under the program. As we stated in the Proposed Rule, we believe it would be an extremely rare occurrence for an ONC–ATCB to have its status revoked and for the National Coordinator to determine that Complete EHRs and/or EHR Modules were improperly certified. If such events were to occur, the regulatory provisions enable the National Coordinator to focus recertification on specific Complete EHRs and/or EHR Modules that were improperly certified in lieu of requiring recertification of all Complete EHRs and EHR Modules tested and certified by the former ONC–ATCB.

In this regard, the National Coordinator has a statutory responsibility to ensure that Complete EHRs and EHR Modules certified under the temporary certification program are in compliance with the applicable certification criteria adopted by the Secretary. We do not believe that the alternatives suggested by the commenters, such as whether a "good faith" eligible professional or eligible hospital can demonstrate meaningful use with a previously certified Complete EHR or EHR Module, would enable the National Coordinator to fulfill this statutory responsibility. Consequently, if the National Coordinator determines that a Complete EHR or EHR Module was improperly certified, then retesting and recertification by an ONC–ATCB are the only means by which to ensure that the Complete EHR or EHR Module satisfies the certification criteria. Moreover, an attestation by a Complete EHR or EHR Module developer and/or user of a Complete EHR or EHR Module would not be an acceptable alternative to retesting and recertification because the National Coordinator could not sufficiently confirm that all applicable certification criteria are met.

We appreciate the concerns expressed by commenters related to the potential financial burden of recertification, the potential legal liability for providers attesting to the use of Certified EHR Technology, and the perceived insufficient amount of time to have a Complete EHR and/or EHR Modules recertified. We believe, however, that some of these concerns may be unfounded. Any decertification of a Complete EHR or EHR Module will be made widely known to the public by ONC through publication on our Web site and list serve, which we believe will help eligible professionals or eligible hospitals identify whether the

certified status of their Certified EHR Technology is still valid. We also believe that programmatic steps, such as identifying ONC–ATCB(s) that could be used for retesting and recertification, could be taken to assist Complete EHR and/or EHR Module developers with achieving timely and cost effective recertifications. Most importantly, in the rare circumstance that recertification is required, we believe that the need to protect the public from potentially unsafe Complete EHRs and/or EHR Modules outweighs the concerns expressed by the commenters. Accordingly, we are finalizing this provision without modification.

K. Sunset of the Temporary Certification Program

We proposed in section 170.490 that the temporary certification program would sunset on the date when the National Coordinator authorized at least one ONC–ACB under the permanent certification program. We further proposed that on the date the sunset occurred, ONC–ATCBs under the temporary certification program would be prohibited from accepting new requests to certify Complete EHRs or EHR Modules. ONC–ATCBs would, however, be able to complete the processing of Complete EHRs and EHR Modules that were being tested and certified at the time the sunset occurred. We clarified that ONC–ATCBs would be able to review any pending applications that they had received prior to the termination date of the temporary certification program and complete the certification process for those Complete EHRs and EHR Modules.

We requested that the public comment on whether we should establish a set date for the temporary certification program to sunset, such as 12/31/2011, instead of a date that depends on a particular action—the authorization of at least one ONC–ACB. We noted that a set date would provide certainty and create a clear termination point for the temporary certification program by indicating to any ONC–ATCBs and other certification bodies that in order to be authorized to certify Complete EHRs and/or EHR Modules after 12/31/2011, they would need to be accredited and reapply to become ONC–ACBs. We further noted that one potential downside to a set date would be the possibility that it would temporarily prevent certifications from being issued during the time period it takes potential ONC–ACB applicants to get accredited and receive their authorizations from the National Coordinator.

Comments. Commenters recommended various methods and means for ending the temporary certification program. The predominant suggestion from commenters was to devise a method for ending the temporary certification program that would limit the amount of uncertainty for vendors, self-developers, and providers. In this regard, multiple commenters recommended a date certain with 12/31/2011 being the only date specified by commenters. Commenters reasoned that a set date would give the industry and market a target for planning purposes. Many commenters, however, stated that a set date was only viable if there were at least one ONC–ACB. Some commenters recommended that there be two ONC–ACBs and some also requested that we ensure that there are one or two accredited testing labs before we sunset the temporary certification program. Commenters contended that having more than one ONC–ACB would help prevent a backlog and potential monopolies.

Multiple commenters recommended that we tie the certification programs with the meaningful use stages (*i.e.,* use the temporary certification program for Stage 1 and the permanent certification program for Stage 2 and beyond) and allow the temporary certification program to continue to certify for Stage 1 until it was no longer needed. One commenter recommended that the temporary certification program should be phased out only after it has been determined that a significant percentage of the industry is ready to move to Stage 2 of the Medicare and Medicaid EHR Incentive Programs.

One commenter proposed that there be a period of overlap of up to a year between the temporary certification program and the permanent certification program to enable ONC–ATCBs to complete the testing and certification of products that were presented prior to the beginning of the permanent certification program. As part of the proposal, the commenter stated that products not completely tested and certified by an ONC–ATCB by the end date would need to be resubmitted under the permanent certification program.

Another commenter recommended that the rules for the transition period must be flexible enough to accommodate an ONC–ATCB to apply to become a testing lab and/or an ONC–ACB under the permanent certification program.

Response. The commenters' recommendation to link the certification programs to the proposed stages of meaningful use illustrates a misunderstanding of the purpose of the certification programs. Consistent with statutory instruction, the primary purpose of the certification programs is to ensure that Complete EHRs, EHR Modules, and possibly other HIT, meet the standards, implementation specifications, and certification criteria adopted by the Secretary. We have proposed a temporary certification program in order to ensure that Certified EHR Technology will be available for the start of the Medicare and Medicaid EHR Incentive Programs and to allow sufficient time for the development of a more rigorous permanent certification program. Linking the temporary certification program to a proposed stage of meaningful use could cause the program to last longer than is necessary, which would be inconsistent with the purpose of the program.

We agree with the majority of commenters that we should strive to achieve as much certainty as possible for the market while also ensuring the existence of a sufficient supply of authorized testing and/or certification bodies so as to enable eligible hospitals and eligible providers to achieve meaningful use. Therefore, we have modified our proposed timeframe such that the temporary certification program will sunset on December 31, 2011, or if the permanent certification program is not fully constituted at that time, then upon a subsequent date that is determined to be appropriate by the National Coordinator. On and after the temporary certification program sunset date, ONC–ATCBs will be prohibited from accepting new requests to test and certify Complete EHRs or EHR Modules. ONC–ATCBs will, however, be permitted up to six months after the sunset date to complete all testing and certification activities associated with requests for testing and certification of Complete EHRs and/or EHR Modules received prior to the sunset date.

We believe that our proposal provides the appropriate balance between market certainty and ensuring that there remains a body authorized to test and certify Complete EHRs and EHR Modules. We believe that many applicants will seek to become ONC–ACBs and that there is sufficient flexibility in the transition to the permanent certification program for ONC–ATCBs either to apply to become ONC–ACBs or to become accredited testing labs. We further believe that applicants will be motivated by business dynamics, such as capturing an increased market share, to become authorized as soon as possible under the permanent certification program.

Therefore, we believe that there will be multiple ONC–ACBs by December 31, 2011.

In the event that the National Coordinator is unable to begin the permanent certification program on January 1, 2012, we believe it is appropriate for the temporary certification program to remain operational until the National Coordinator determines that the permanent certification program is fully constituted. As stated above, keeping the temporary certification program operational will help ensure that a body authorized to test and certify Complete EHRs and EHR Modules remains available. This flexibility provided to the National Coordinator will help to alleviate the "consumer" concerns expressed by commenters related to the potential existence of backlogs or monopolies at the start of the permanent certification program. In determining whether the proposed permanent certification program is fully constituted, the National Coordinator will consider whether there are a sufficient number of ONC–ACBs and accredited testing laboratories to address the current market demand. For example, if multiple ONC–ATCBs exist, but only one ONC–ACB has been authorized and no testing laboratories are accredited (or alternatively one or more testing laboratories exist, but no ONC–ACBs), and the Secretary will soon issue newly adopted standards, implementation specifications and certification criteria, then it is unlikely that the permanent certification program would be considered fully constituted. We believe this approach sufficiently addresses the concerns expressed by various commenters and provides the most assurance to the market, particularly for Complete EHR and EHR Module developers that seek testing and certification of Complete EHRs and/or EHR Modules.

Consistent with our original proposal, we are allowing ONC–ATCBs to complete the processing of all requests for the testing and certification of Complete EHRs and/or EHR Modules received prior to the sunset date. By completing the processing of a request, we expect that all testing and certification activities would be completed including the issuance of a certification, if appropriate. We are limiting the time to complete the processing of requests to a period of six months after the sunset date of the temporary certification program. We agree with the commenter that a limitation is necessary to bring finality to the temporary certification program. We believe that six months is a more appropriate period than "up to a year" because, as previously stated, we anticipate the next set of standards, implementation specifications, and certification criteria to be published in late summer of 2012. Therefore, market confusion can be avoided by ending all vestiges of the temporary certification program before the start of testing and certification to newly adopted standards, implementation specifications, and certification criteria. If the testing and certification of a Complete EHR or EHR Module is not completed prior to the end of the 6-month period, the Complete EHR or EHR Module would have to be resubmitted for testing and certification under the permanent certification program.

L. Recognized Certification Bodies as Related to the Physician Self-Referral Prohibition and Anti-Kickback EHR Exception and Safe Harbor Final Rules

The physician self-referral prohibition exception and anti-kickback statute safe harbor for donations of EHR software (42 CFR 411.357(w) and 42 CFR 1001.952(y), respectively) include among their conditions a provision that donated software must be interoperable and that, for purposes of the exception and safe harbor, software is deemed to be interoperable "if a certifying body recognized by the Secretary has certified the software within no more than 12 months prior to the date it is provided to the [recipient]." This final rule addresses the process in which the Secretary recognizes a certifying body. As to the process, we requested comment in the Proposed Rule on whether we should construe the proposed "authorization" process for ONC–ATCBs and ONC–ACBs as the Secretary's method for "recognizing" certification bodies.

Comments. The vast majority of commenters supported replacing the Secretary's current method for "recognizing" certification bodies with the proposed "authorization" process for ONC–ATCBs and ONC–ACBs. The commenters reasoned that our proposal offered consistency and efficiency for all stakeholders involved. Only one commenter recommended that the current process for "recognizing" certification bodies not be superseded by the proposed "authorization" process, but that commenter did so based on a concern expressed by multiple commenters. The concern was over whether the proposed "authorization" process would negatively affect donations of "certified EHRs" currently in progress, including the invalidation of existing investments and the disruption of pending and executed contracts as well as ongoing EHR installations. To address these concerns, some commenters recommended that EHRs certified by a "recognized certification body" continue to be permitted for donation under the exception and safe harbor if they still satisfied the parameters set by the physician self-referral prohibition exception and anti-kickback statute safe harbor final rules. The commenters also recommended that the subsequent "rollout" of EHR installations to physician offices should be deemed to qualify for the exception and safe harbor based on certification status as of the original purchase date, regardless of the date of actual installation in physician offices.

Some commenters recommended that the term of recognition for certified EHR technology under the exception and safe harbor should be equal to the "certification time period of two (2) years, and not 12 months as currently specified." Another commenter recommended that any EHR certified by the Certification Commission for Health Information Technology (CCHIT) should continue to qualify for the exception and safe harbor at least through the end of Stage 1 of the Medicare and Medicaid EHR Incentive Programs.

One commenter noted that the physician self-referral prohibition exception and anti-kickback statute safe harbor final rules define "interoperability" and that an EHR's ability to be interoperable is a factor in its ability to be donated under those rules. The commenter requested that the National Coordinator clarify and provide guidance on the standards and interoperability requirements to which ONC–ATCBs and ONC–ACBs would test and certify EHRs for purposes of the exception and safe harbor.

A commenter recommended that we clarify that Complete EHRs and EHR Modules that are certified under the temporary or permanent certification programs *may* be deemed interoperable and *may* qualify for the physician self-referral prohibition exception or the anti-kickback statute safe harbor for EHR donations. The commenter also recommended that we state that Complete EHRs and EHR Modules will also be required to meet other regulatory provisions outlined in 42 CFR 411.351 *et seq.* or 1001.952 in order to qualify for the exception or safe harbor (*e.g.,* an EHR must be used for any patient without regard to payer status). The commenter proposed that we include a new requirement that a certifying body cannot certify EHRs or EHR Modules if they unnecessarily limit or restrict their

use or compatibility with other HIT (*e.g.,* if an entity binds physicians to a particular entity to receive the EHR or the EHR Module, or uses a combination of certified EHR Modules that do not work together).

Response. We appreciate the commenters' support for our proposal to incorporate the current "recognition" of certification bodies into the ONC–ATCB and ONC–ACB "authorization" processes. We agree with commenters that folding the "recognition" process into the ONC–ATCB and ONC–ACB "authorization" processes will lead to greater clarity and consistency for all stakeholders. Accordingly, the ONC–ATCB and ONC–ACB "authorization" processes will constitute the Secretary's "recognition" of a certification body.

This final rule only addresses the issue of how the Secretary recognizes a certifying body. It does not address issues related to the application of the exception or safe harbor, as those issues are beyond the scope of this final rule and are better directed to CMS and OIG, respectively. As noted in the Proposed Rule, CCHIT is the only organization that has both applied for and been granted "recognized certification body" status under ONC's Certification Guidance Document (CGD). As implied in the Proposed Rule and the CGD, all "recognized certification bodies" will lose their status upon the effective date of this final rule. As a result, they will need to reapply to become an ONC–ATCB (and in the future an ONC–ACB) in order to be a "recognized certification body" after the effective date of this final rule. Loss of "recognized" status under the CGD upon the effective date of this final rule does not impact the fact that certifications made by CCHIT while recognized under the CGD were made by a "recognized certification body."

With respect to the request for clarification regarding the standards and interoperability requirements to which ONC–ATCBs and ONC–ACBs would test and certify Complete EHRs and EHR Modules, we clarify that we will not adopt different or additional certification criteria to which Complete EHRs or EHR Modules must be tested and certified in order to meet the deeming provision, and we do not expect ONC–ATCBs and ONC–ACBs to use different certification criteria to test and certify Complete EHRs and EHR Modules. We believe that the certification criteria adopted by the Secretary specify several important interoperability requirements and build the foundation for more advanced interoperability in the future. It is also important to note that regardless of whether EHRs certified in 2009 or 2010 by a "recognized certification body" qualify for donation under the EHR exception and safe harbor, these EHRs will not meet the definition of Certified EHR Technology and therefore must be recertified by an ONC–ATCB in order to be used by an eligible professional or eligible hospital to demonstrate meaningful use.

All other issues raised by commenters are outside the scope of this rulemaking and in many cases would require notice and comment rulemaking in order to be appropriately addressed.

M. Grandfathering

Grandfathering would essentially involve a determination by the National Coordinator that existing EHR systems developed by vendors and self-developers, as well as those systems being used by providers in a possible modified state, are equivalent to the definition of Certified EHR Technology and thus are capable of being used to achieve meaningful use. Although we did not propose or discuss the concept of grandfathering in the Proposed Rule, several commenters made recommendations on the subject.

Comments. On all three recent meaningful use related rulemakings (the HIT Standards and Certification Criteria interim final rule, the Medicare and Medicaid EHR Incentive Programs proposed rule, and the HIT Certification Programs proposed rule), HHS received comments related to the concept of "grandfathering" existing EHRs in some form or another. Some comments requested that we deem all CCHIT-certified EHRs from 2008 onward to be Certified EHR Technology. Others requested that we deem all existing EHRs regardless of whether these EHRs had been certified by CCHIT. In both cases, these commenters argued that this would enable eligible professionals and eligible hospitals who were early adopters to possess HIT that met the definition of Certified EHR Technology right away. One commenter offered a variant to this suggestion by adding a qualification that we should only deem EHRs if the EHR currently in the possession of an eligible professional or eligible hospital could enable them to meet some (at least 5) number of meaningful use objectives. While other commenters using this same line of reasoning believed that an EHR should qualify for grandfathering if it could enable an eligible professional or eligible hospital to meet all applicable objectives and measures, but that such certification would only be valid until the temporary certification program was operational. One commenter specifically recommended that ONC establish a petition process whereby an individual eligible professional or eligible hospital could apply directly to ONC for a waiver to use a non-certified EHR to qualify for meaningful use.

Response. We believe that this final rule is the most appropriate rulemaking to address comments on grandfathering. The definition of Certified EHR Technology specified by Congress at section 3000 of the PHSA set forth clear parameters that dictate when HIT will be considered Certified EHR Technology. To be Certified EHR Technology, HIT must first meet the definition of a Qualified EHR, which in turn must be certified pursuant to the certification program(s) established under section 3001(c)(5) by the National Coordinator as meeting standards adopted under section 3004 by the Secretary. Certification is used to provide consumers with assurance and confidence that the product or service they seek to purchase and use will work as expected and will include the capabilities for which it was purchased.

While grandfathering may appear convenient in that it would allow eligible professionals and eligible hospitals to use the HIT they already have in place, we believe that in this context grandfathering is inappropriate and would be inconsistent with the statutory requirements for Certified EHR Technology specified in the PHSA. Grandfathering provides neither assurance nor confidence for eligible professionals and eligible hospitals that their existing HIT will have the capacity to support their attempts to meet meaningful use Stage 1 objectives and measures. In this regard, we do not believe that the variations to "grandfathering" some commenters suggested (that an EHR should be grandfathered if it could enable an eligible professional or eligible hospital to meet some or all applicable meaningful use objectives and measures) are valid approaches. Conversely, we believe those approaches are risky from a programmatic perspective with respect to the potential for fraud, and from an eligible professional or eligible hospital's perspective in that they would have no demonstrable proof that their EHR possessed the capabilities necessary to meet the certification criteria adopted by the Secretary. More importantly, if we were to permit grandfathering according to the logic expressed by these commenters, the only way we, and the commenters, would be able to tell if an EHR should legitimately be deemed grandfathered would be if the eligible professional or eligible hospital had successfully

achieved meaningful use. We question whether commenters would be willing to take the risk of attempting meaningful use without the certainty of knowing that their EHR provided the capabilities they would need to attempt to achieve it.

Furthermore, while a deeming of this sort may address a very short term need of existing HIT users, we believe it would significantly undercut our long-term policy goals and objectives, as well as provide eligible professionals and eligible professionals with a false sense of security. Without the assurances provided by the testing and certification process, grandfathering would require HHS to permit eligible professionals and eligible hospitals to use HIT that may be incapable from the start of supporting their achievement of meaningful use Stage 1. Along those lines, we do not believe that the petition and waiver process a commenter suggested is a feasible option because HHS would incur the risk that eligible professionals and eligible hospitals would fail to achieve meaningful use Stage 1 because their existing HIT is incapable of meeting the applicable objectives and measures even though we had deemed it "certified."

N. Concept of "Self-Developed"

We stated in the Proposed Rule that we interpreted the HIT Policy Committee's use of the word "self-developed" to mean a Complete EHR or EHR Module that has been designed, modified, or created by, or under contract for, a person or entity that will assume the total costs for its testing and certification and will be a primary user of the Complete EHR or EHR Module. We noted that self-developed Complete EHRs and EHR Modules could include brand new Complete EHRs or EHR Modules developed by a health care provider or their contractor. We further noted that it could also include a previously purchased Complete EHR or EHR Module which is subsequently modified by the health care provider or their contractor and where such modifications are made to capabilities addressed by certification criteria adopted by the Secretary. We specifically stated that we would limit the scope of "modification" to only those capabilities for which the Secretary has adopted certification criteria because other capabilities (*e.g.,* a different graphical user interface (GUI)) would not affect the underlying capabilities a Complete EHR or EHR Module would need to include in order to be tested and certified. Accordingly, we stated that we would only refer to the Complete EHR or EHR Module as "self-developed" if the health care provider paid the total costs to have the Complete EHR or EHR Module tested and certified.

Comments. Multiple hospitals and hospital associations requested that we clarify the definition of "self-developed" to include an indication of the extent to which modifications can be made to previously certified Complete EHRs or EHR Modules without requiring a system to be certified as "self-developed." The commenters noted that we have clearly stated that eligible professionals and eligible hospitals bear full responsibility for making certified EHR Modules work together. Therefore, the commenters contended that providers must have the ability to make needed modifications to certified EHR Modules to achieve that purpose. The commenters stated that often there is a need for custom configurations or settings within the parameters of certified EHRs, including modifications that may be necessary to ensure that the EHR works properly when implemented within an organization's entire HIT environment. The commenters further stated that such modifications may affect, or even enhance, the capabilities addressed by the certification criteria by providing additional and specific decision-support functions or allowing for additional quality improvement activities. The commenters asserted that as long as the system can still perform the function for which it was originally certified, these modifications should not trigger the need for a self-developed certification, even if the changes are made to the capabilities addressed by the certification criteria.

The commenters stated clarity was needed due to the substantial resources that will be required for certification of self-developed systems. In addition, commenters stated that, for legal compliance purposes, clarity will allow providers to confidently submit attestations to federal and state agencies about the certification status of the Certified EHR Technology they use.

Response. We understand the unique needs and requirements eligible professionals and eligible hospitals have with respect to successfully implementing and integrating HIT into operational environments. We provided a description of the term "self-developed" in the Proposed Rule's preamble for two reasons. First, in order to provide greater clarity for stakeholders regarding who would be responsible for the costs associated with testing and certification and, second, to clearly differentiate in our impact analysis those Complete EHRs and EHR Modules that would be certified once and most likely sold to many eligible professionals and eligible hospitals from those that would be certified once and used primarily by the person or entity who paid for the certification. We believe that many commenters were not concerned about the fact that brand new, built from scratch self-developed Complete EHRs and EHR Modules would need to be tested and certified. Rather, it appeared that commenters were concerned about whether any modification to an *already certified* Complete EHR or EHR Module, including those that would be enhancements or required to integrate several EHR Modules, would invalidate a certification or certifications and consequently require the eligible professional or eligible hospital to seek a new certification because it would be considered self-developed. We believe this concern stems from the following statement we made in the preamble of the Proposed Rule.

> Self-developed Complete EHRs and EHR Modules could include brand new Complete EHRs or EHR Modules developed by a health care provider or their contractor. It could also include a previously purchased Complete EHR or EHR Module which is subsequently modified by the health care provider or their contractor and where such modifications are made to capabilities addressed by certification criteria adopted by the Secretary. We limit the scope of "modification" to only those capabilities for which the Secretary has adopted certification criteria because other capabilities (*e.g.,* a different graphical user interface (GUI)) would not affect the underlying capabilities a Complete EHR or EHR Module would need to include in order to be tested and certified.

In response to these concerns, we would like to further clarify the intent of our statements, specifically the statement that a self-developed Complete EHR or EHR Module "could also include a previously purchased Complete EHR or EHR Module which is subsequently modified by the health care provider or their contractor and where such modifications are made to capabilities addressed by certification criteria adopted by the Secretary." We agree with commenters that not every modification would or should constitute a modification such that a Complete EHR or EHR Module's certified status would become invalid. We provided an example in the proposed rule, quoted above, that spoke to modifications not related to any of the capabilities addressed by certification criteria adopted by the Secretary. We did not, however, provide any additional information regarding what we would consider an appropriate or inappropriate modification to an already certified Complete EHR or EHR Module

and now take the opportunity to provide that clarification.

We recognize that a certified Complete EHR or certified EHR Module may not automatically work "out of the box" once it is implemented in an operational environment. We also cautioned eligible professionals and eligible hospitals in the HIT Standards and Certification Criteria interim final rule that, if they chose to use EHR Modules to meet the definition of Certified EHR Technology, they alone would be responsible for properly integrating multiple EHR Modules. Given that many of the certification criteria adopted by the Secretary express minimum capabilities, which may be added to or enhanced by eligible professionals and eligible hospitals to meet their health care delivery needs (*e.g.,* more than five rules could be added to the clinical decision support capability), we believe that it is unrealistic to expect that the certified capabilities of a Complete EHR or EHR Module will remain 100% unmodified in all cases. As a result, we believe it is possible for an eligible professional or eligible hospital to modify a Complete EHR or EHR Module's certified capability provided that due diligence is taken to prevent such a modification from adversely affecting the certified capability or precluding its proper operation. While we cannot review every eligible professional and eligible hospital's use of Certified EHR Technology and every potential modification that may be made to determine whether such modification may have invalidated a Complete EHR or EHR Module's certification, we strongly urge eligible professionals and eligible hospitals to consider the following. Certification is meant to provide assurance that a Complete EHR or EHR Modules will perform according to the certification criteria to which they were tested and certified. Any modification to a Complete EHR or EHR Module after it has been certified has the potential to jeopardize the proper operation of the Complete EHR or EHR Module and thus the eligible professional or eligible hospital's ability to achieve meaningful use. If an eligible professional or eligible hospital would like absolute assurance that any modifications made did not impact the proper operation of certified capabilities, they may find it prudent to seek to have the Complete EHR or EHR Module(s) retested and recertified.

O. Validity of Complete EHR and EHR Module Certification and Expiration of Certified Status

In the Proposed Rule, we discussed the validity of "certified status" of Complete EHRs and EHR Modules, as well as the expiration of that status as it related to the definition of Certified EHR Technology. We stated that certification represented "a snapshot, a fixed point in time, where it has been confirmed that a Complete EHR or EHR Module has met all applicable certification criteria adopted by the Secretary." We went on to say that as the Secretary adopts new or modified certification criteria, the previously adopted set of certification criteria would no longer constitute all of the applicable certification criteria to which a Complete EHR or EHR Module would need to be tested and certified. Thus, we clarified that after the Secretary has adopted new or modified certification criteria, a previously certified Complete EHR or EHR Module's certification would no longer be valid for purposes of meeting the definition of Certified EHR Technology. In other words, because new or modified certification criteria had been adopted, previously issued certifications would no longer indicate that a Complete EHR or EHR Module possessed all of the capabilities necessary to support an eligible professional's or eligible hospital's achievement of meaningful use. Accordingly, we noted that Complete EHRs and EHR Modules that had been certified to the previous set of adopted certification criteria would no longer constitute "Certified EHR Technology."

We also discussed that the planned two-year schedule for updates to meaningful use objectives and measures and correlated certification criteria created a natural expiration with respect to the validity of a previously certified Complete EHR's or EHR Module's certified status and its continued ability to be used to meet the definition of Certified EHR Technology. We stated that after the Secretary has adopted new or modified certification criteria, previously certified Complete EHRs and EHR Modules must be retested and recertified in order to continue to qualify as Certified EHR Technology.

We offered further clarification by stating that regardless of the year and meaningful use stage at which an eligible professional or eligible hospital enters the Medicare or Medicaid EHR Incentive Program, the Certified EHR Technology that would need to be used would have to include the capabilities necessary to meet the most current certification criteria adopted by the Secretary at 45 CFR part 170 subpart C in order to meet the definition of Certified EHR Technology. Finally, we asked for public comment on the best way to assist eligible professionals and eligible hospitals who begin meaningful use in 2013 or 2014 (at Stage 1) in identifying Complete EHRs and/or EHR Modules that have been certified to the most current set of adopted certification criteria and therefore could be used to meet the definition of Certified EHR Technology.

Comments. Several commenters disagreed with our position. Other commenters agreed and contended that Certified EHR Technology should always be as up-to-date and as current as possible. Of those commenters that disagreed, their concerns focused on two areas: The validity/expiration of certified status and how eligible professionals and eligible hospitals who adopt Certified EHR Technology in the year before we anticipate updating adopted standards, implementation specifications, and certification criteria for a future stage of meaningful use would be affected.

Commenters asserted that some certification criteria were unlikely to change between meaningful use stages and that a Complete EHR or EHR Module's certification should remain valid and not expire until the Secretary had adopted updated certification criteria. These commenters requested that ONC only make changes to certification criteria on a cyclical basis and only when necessary for meaningful use or to advance interoperability. Finally, within the context of their responses, many of these commenters signaled favorable support for our proposal to include "differential certification" in the permanent certification program. In that regard, some commenters noted that we should not require Complete EHRs and EHR Modules certified under the purview of the temporary certification program to be fully retested and recertified once the permanent certification program has been initiated.

A number of commenters expressed concerns about our position and contended that it required eligible professionals and eligible hospitals who adopt Certified EHR Technology in 2012 (to attempt meaningful use Stage 1) to upgrade their Certified EHR Technology twice in two years (according to the proposed meaningful use stage staggering) in order to continue to be eligible for meaningful use incentives during 2013 when they would only still have to meet meaningful use Stage 1. Some of these commenters viewed this as a penalty and disagreed with our

position that eligible professionals and eligible hospitals should have to use Certified EHR Technology that had been certified to the most recently adopted certification criteria. Additionally, these commenters conveyed their belief that it is not in the best interest of eligible professionals and eligible hospitals to require that they use Certified EHR Technology that includes more advanced capabilities than are necessary to qualify for the meaningful use stage that they are attempting to meet. Finally, one commenter requested that we offer a graphical depiction to more clearly convey our position.

Response. We appreciate commenters' support for our proposal for differential certification. Because this concept is solely relevant to the policies of the permanent certification program, we do not address it in this final rule.

As previously mentioned in both the HIT Standards and Certification Criteria interim final rule and the Medicare and Medicaid EHR Incentive Programs proposed rule, ONC and CMS anticipate that the requirements for meaningful use will be adjusted every two years. We do not expect to adopt certification criteria more frequently than every two years. In its proposed rule (75 FR 1854), CMS also indicated that "[t]he stages of criteria of meaningful use and how they are demonstrated are described further in this proposed rule and will be updated in subsequent proposed rules to reflect advances in HIT products and infrastructure. *This could include updates to the Stage 1 criteria in future rulemaking.*" (Emphasis added.)

We believe that commenters who expressed concerns and objected to our discussion of the expiration/validity of a Complete EHR or EHR Module's certified status did not account for the real possibility that the requirements for an eligible professional or eligible hospital to meet meaningful use Stage 1 in 2013 (or 2014) could be different and possibly more demanding than they were for meaningful use Stage 1 in 2012. Contrary to some commenters' assumptions, it is possible that while establishing the objectives and measures for meaningful use Stage 2 (in a subsequent rulemaking) that CMS could revise what it means to meet meaningful use Stage 1 in 2013. Consequently, such revisions could include additional requirements, based on advances in HIT, beyond the requirements that will be established in the forthcoming final rule that specifies what meaningful use Stage 1 will require in 2011 and 2012. Therefore, the potential remains that an eligible professional or eligible hospital who becomes a meaningful user in 2012 would need additional, not currently present, capabilities from Certified EHR Technology in order to meet meaningful use Stage 1 requirements in 2013.

In this regard, and consistent with the caveat many commenters articulated, we identified that an eligible professional or eligible hospital would no longer be able to assert that a Complete EHR or EHR Module's certification was valid for purposes of satisfying the definition of Certified EHR Technology in subsequent years for at least two reasons: (1) The certification criteria related to particular capabilities had been modified; and/or (2) the standard(s) and implementation specification(s) associated with a certification criterion had been modified (newly adopted or replaced). With respect to either of these two reasons, in order for a Complete EHR or EHR Module to continue to meet the definition of Certified EHR Technology, it would need to be retested and recertified to the new certification criteria or newly adopted standards and/or implementation specifications for the subsequent years for which they had been adopted. Only then would an eligible professional or eligible hospital be able to assert that it continues to possess a Complete EHR or EHR Module with a valid certification that could be used to meet the definition of Certified EHR Technology. For example, a Complete EHR would need to be retested and recertified as being compliant with a newly adopted standard for the 2013/2014 certification period in order for a Complete EHR developer, an eligible professional, or an eligible hospital to validly assert that the certification issued for the Complete EHR enables it to meet the definition of Certified EHR Technology. As we stated in the Proposed Rule, if the previously certified Complete EHR were not retested and recertified as being compliant with the newly adopted standard, it would not "lose its certification." However, the previous certification would no longer enable the Complete EHR to meet the definition of Certified EHR Technology. Many commenters recognized this fact by indicating that in situations where interoperability was a focus, retesting and recertification would be needed and justified. With respect to the validity of a Complete EHR or EHR Module's certification, we ask commenters to consider how they would expect to meet a subsequent stage of meaningful use without the technical capabilities necessary to do so. A Complete EHR or EHR Module's certification is only as good as the capabilities that can be associated with that certification. If the Secretary adopts new standards, implementation specifications, or certification criteria, a Complete EHR or EHR Module may no longer provide a valid set of capabilities to satisfy the definition of Certified EHR Technology or support an eligible professional's or eligible hospital's attempt to achieve a particular meaningful use stage.

Accordingly, and because the HITECH Act requires eligible professionals and eligible hospitals to use Certified EHR Technology in order to qualify for incentive payments, we reaffirm our previous position. Regardless of the year and meaningful use stage at which an eligible professional or eligible hospital enters the Medicare or Medicaid EHR Incentive Program, the Certified EHR Technology that they would need to use would have to include the capabilities necessary to meet the most current certification criteria adopted by the Secretary at 45 CFR 170 subpart C. We believe that this position takes into account the best interests of eligible professionals and eligible hospitals. It will also serve to assure eligible professionals and eligible hospitals who implement HIT that meets the definition of Certified EHR Technology that they will have the requisite technical capabilities to attempt to achieve meaningful use. Just as important, this position ensures that *all* Certified EHR Technology will have been tested and certified to the same standards and implementation specifications and provide the same level of interoperability, which would not be the case if we were to permit different variations of Certified EHR Technology to exist.

To further address concerns raised by the commenters, we clarify that if the temporary certification program sunsets on December 31, 2011 and the permanent certification program is fully constituted at the start of 2012, Complete EHRs and EHR Modules that were previously certified by ONC–ATCBs to the 2011/2012 certification criteria adopted by the Secretary will not need to be retested and recertified as having met the certification criteria for those years. In other words, the fact that the permanent certification program had replaced the temporary certification program would not automatically invalidate certifications that were previously issued by ONC–ATCBs pursuant to the 2011/2012 certification criteria.

However, we reiterate for commenters what we stated in the Proposed Rule (75 FR 11351): "[S]ince a new certification program would exist, which would include different processes, we emphasize that Complete EHRs and

EHR Modules tested and certified under the temporary certification program by an ONC–ATCB would need to be tested and certified according to the permanent certification program once the Secretary adopts certification criteria to replace, amend, or add to previously adopted certification criteria." Thus, once the permanent certification program is fully constituted and after the Secretary has adopted additional or revised certification criteria (which we expect will occur approximately two years from now), *all* Complete EHRs and EHR Modules that were previously certified under the temporary certification program by ONC–ATCBs will need to be tested by an accredited testing laboratory and certified by an ONC–ACB. Pursuant to our discussion regarding the sunset of the temporary certification program combined with the two year cycle on which we expect to adopt certification criteria, we anticipate the testing and certification of Complete EHRs and EHR Modules to the 2013/2014 certification criteria would need to begin by mid-2012 in order for Complete EHRs and EHR Modules to be retested and recertified prior to the start of the next meaningful use reporting period.

We provide the following illustration overlaid on CMS's proposed staggered payment year/adoption year chart for the Medicare program to more clearly convey the discussion above. This illustration would also be applicable to the Medicaid program.

First payment year	Payment year			
	2011	2012	2013	2014
2011	Stage 1	Stage 1	Stage 2	Stage 2.
2012		Stage 1	Stage 1	Stage 2.
2013			Stage 1	Stage 2.
2014				Stage 1.
	Complete EHRs and EHR Modules certified by ONC–ATCBs or ONC–ACBs [1] to certification criteria adopted for 2011 & 2012 meet the definition of Certified EHR Technology.		Complete EHRs and EHR Modules certified by ONC–ACBs to certification criteria adopted for 2013 & 2014 meet the definition of Certified EHR Technology.	

Comments. In response to our question about how to best indicate to eligible professionals and eligible hospitals those Complete EHRs and/or EHR Modules certified to the most current set of adopted certification criteria (which could be used to meet the definition of Certified EHR Technology), several commenters offered suggestions regarding "labeling" conventions for Complete EHRs and EHR Modules. Overall, commenters indicated that specific "labeling" parameters would help clarify the "currency" of a Complete EHR or EHR Module's certification and whether the certification was valid. These commenters offered a variety of suggested techniques, including identifying Complete EHRs and EHR Modules according to: the applicable meaningful use stage they could be used for; the month and year they had been tested and certified; and the year associated with the most current set of adopted standards, implementation specifications, and certification criteria. Additionally, in light of the EHR Module "bundle" concept we proposed with respect to when EHR Modules need to be tested and certified to adopted privacy and security criteria, one commenter recommended that we assign specific "labeling" constraints to certifications issued to pre-coordinated, integrated bundles of EHR Modules. Another comment suggested "labeling" constraints be assigned when a Complete EHR or EHR Module had been tested at an eligible professional or eligible hospital's site (*e.g.,* at the hospital where the Complete EHR is deployed).

Response. We agree with the commenters who requested more specific requirements surrounding how a Complete EHR or EHR Module's certified status should be represented and communicated and believe that it will provide the most benefit to eligible professionals and eligible hospitals who are interested in easily identifying Complete EHRs and EHR Modules that have been tested and certified by an ONC–ATCB. In fact, Guide 65, Section 14, requires evidence of policies and procedures for use and display of certificates (*e.g.,* logos). We proposed and, as discussed above, will require applicants for ONC–ATCB status to provide the National Coordinator with a copy of their policies related to the use and display of certificates. We believe that the most effective method to ensure that the certified status of a Complete EHR or EHR Module is appropriately represented and communicated is through the addition of a new principle to the Principles of Proper Conduct for ONC–ATCBs. This new Principle of Proper Conduct will also provide additional clarity for applicants in terms of the information that the National Coordinator expects to be contained in the copy of the policies and procedures associated with the use and display of certificates submitted by an applicant as part of its application.

Accordingly, we also believe that this new Principle of Proper Conduct for ONC–ATCBs related to how a Complete EHR or EHR Module's certification is communicated is a logical extension of our proposals, is similar to the requirement we place on ONC–ATCBs with respect to how they represent themselves, and provides more specificity and clarity around requirements to which ONC–ATCBs would already be subject. The new Principle of Proper Conduct requires that:

- All certifications must require that a Complete EHR or EHR Module developer conspicuously include the following text on its Web site and in all marketing materials, communications statements, and other assertions related to the Complete EHR or EHR Module's certification:
  - "This [Complete EHR or EHR Module] is 201[X]/201[X] compliant and has been certified by an ONC–ATCB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services or guarantee the receipt of incentive payments."; and
  - The information an ONC–ATCB is required to report to the National Coordinator for the specific Complete EHR or EHR Module at issue.
- A certification issued to an integrated bundle of EHR Modules shall be treated the same as a certification

[1] If the permanent certification program is fully constituted and the temporary certification program sunsets on 12/31/2011, all new requests made after 12/31/2011 for certification of Complete EHRs or EHR Modules to the 2011/2012 certification criteria will be processed by an ONC–ACB.

issued to a Complete EHR for the purposes of the above requirement except that it must also indicate each EHR Module that comprises the bundle.

With respect to the requirement that includes "201[X]/20'[X]," we expect ONC–ATCBs to put the years "2011/2012" where we have provided for variability in the date range and have only provided this flexibility in the rare circumstance that the temporary certification program does not sunset according to the schedule that we have discussed. Given our clarifications about the validity of a Complete EHR or EHR Module's certification, we believe that it would be inappropriate and misleading to adopt an identification requirement solely associated with meaningful use stages. We also believe that it would be inappropriate to constrain a particular certification based on whether the certification could be attributed to a particular entity at a particular location. While unlikely, we do not want to presume that such a certified Complete EHR or EHR Module would or could not be useful to another eligible professional or eligible hospital.

We do, however, agree with the commenter who suggested the specific constraint for a bundle of EHR Modules. Such bundles, by their very nature, would otherwise constitute a Complete EHR and therefore must be integrated in such a way in order to even be tested and certified as a bundle. In the case of a bundle of EHR Modules, the bundle is greater than the sum of each individual EHR Module, and for that reason, we would like to clarify that EHR Modules, once certified as part of a bundle, would not separately inherit a certification just because they were certified as part of a bundle. For example, if EHR Modules A, B, C, and D, are certified as an integrated bundle, EHR Module C would not on its own be certified, just by virtue of the fact that it was part of a certified bundle. If an EHR Module developer wanted to make EHR Module C available for uses outside the bundle, then they would have to seek to have EHR Module C separately tested and certified.

Comments. Several commenters requested that we clarify whether every single updated version of a Complete EHR or EHR Module would need to be retested and recertified in order to have a valid certification and whether there would be a mechanism available to accommodate routine changes and product maintenance without the need to fully retest and recertify each instantiation of a previously certified Complete EHR or EHR Module. Some of these commenters stressed that they provide bug-fixes and other maintenance upgrades to customers on a regular basis and that those versions are normally denoted by a new "dot release" (*e.g.,* version 7.1.1 when 7.1 received certification).

Response. We understand that Complete EHR and EHR Module developers will conduct routine maintenance. We also recognize that at times Complete EHR and EHR Module developers will provide new or modified capabilities to either make the Complete EHR or EHR Module perform more efficiently and/or to improve user experiences related to certain functionality (*e.g.,* a new graphical user interface (GUI)). Our main concern, as we stated in the preamble, is whether these changes adversely affect the capabilities to which a Complete EHR or EHR Module has already been tested and certified and whether those changes are such that the Complete EHR or EHR Module would no longer support an eligible professional or eligible hospital's achievement of meaningful use. Accordingly, we clarify that a previously certified Complete EHR or EHR Module may be updated for routine maintenance or to include new capabilities that both affect capabilities related and unrelated to the certification criteria adopted by the Secretary without its certification becoming invalid.[2] However, we do not believe that it would be wise to simply permit a Complete EHR or EHR Module developer to claim without any verification that the routine maintenance or new/modified capabilities included in a new version did not adversely affect the proper functioning of the previously certified capabilities. We believe that an ONC–ATCB should, at a minimum, review an attestation submitted by a Complete EHR or EHR Module developer indicating the changes that were made, the reasons for those changes, and other such information and supporting documentation that would be necessary to properly assess the potential effects the new version would have on previously certified capabilities.

As a result, we have added to both § 170.445 and § 170.450 a requirement that an ONC–ATCB must accept requests for an updated version of a previously certified Complete EHR or EHR Module to inherit the previously certified Complete EHR or EHR Module's issued certification without being retested and recertified. However, the Complete EHR or EHR Module developer must submit an attestation as described above in the form and format specified by the ONC–ATCB that the newer version does not adversely affect the proper functionality of previously certified capabilities. Upon receipt of the attestation, an ONC–ATCB would be permitted to determine whether the updates and/or modifications are such that the new version would adversely affect previously certified capabilities and therefore need to be retested and recertified, or whether to grant certified status to the new version derived from the previously certified Complete EHR or EHR Module.

If the ONC–ATCB awards a certification to a newer version of a previously certified Complete EHR or EHR Module, we expect the ONC–ATCB to include this issued certification in its weekly report to the National Coordinator. We note that aside from specifying an ONC–ATCB must provide this mechanism and review the submitted attestation, we do not specify the fees or any other processes an ONC–ATCB may determine necessary before granting certified status to a newer version of a previously certified Complete EHR or EHR Module based on the submitted attestation.

P. General Comments

We received comments that were not attributable to a specific provision or proposal in the Proposed Rule, but were still within the scope of the temporary certification program. These comments were on such matters as the timing of the temporary certification program, the use of elements in the proposed permanent certification program for the temporary certification program, the potential for a backlog of requests for testing and certification, the costs of testing and certification, the use and testing of open source Complete EHRs or EHR Modules, and the safety of Complete EHRs and EHR Modules.

Comments. One commenter suggested that we not implement the temporary certification program. Rather, the commenter suggested that we proceed straight to implementing the permanent certification program. Some other commenters suggested we were moving too fast, while still other commenters suggested we were not moving fast enough in implementing the temporary certification program. Some commenters

[2] We understand that Complete EHR and EHR Module developers typically consider a "minor version release" to be, for example, a version number change from 3.0 to 3.1 and consider a "major version release" to be, for example, a version number change from 4.0 to 5.0. In providing for this flexibility, we do not presume the version numbering schema that a Complete EHR or EHR Module developer may choose to utilize. As a result, we do not preclude a Complete EHR or EHR Module developer from submitting an attestation to an ONC–ATCB for a Complete EHR or EHR Module whose version number may represent a minor or major version change.

suggested utilizing elements that we proposed for the permanent certification program, such as accreditation and post market surveillance in the temporary certification program.

Response. We discussed in detail the urgency for establishing the temporary certification program, particularly the need for making Certified EHR Technology available so that eligible professionals and eligible hospitals would have the ability to attempt to achieve meaningful use Stage 1. In discussing this urgency and the differences between the temporary certification program and the permanent certification program, we explained how there was not sufficient time to implement such elements as accreditation and post market surveillance. If we were to attempt to establish an accreditation process, Certified EHR Technology would likely not be available in a timely manner. Further, the limited time that we anticipate the temporary certification program being in existence prevents us from establishing a post market surveillance program. By the time we would be able to establish and get results from a post market surveillance program, the temporary certification program will likely have sunset.

Comments. Commenters requested that we prevent testing and certification monopolies and backlogs of requests for testing and certification. Commenters also requested that we mandate pricing for testing and certification or at least establish a reasonable fee requirement.

Response. We believe that through the policies we have established in this final rule that the temporary certification program is inclusive of as many potential applicants for ONC–ATCB status as possible and that we have created an environment that is likely to result in multiple ONC–ATCBs. Further, we believe that multiple ONC–ATCBs and market dynamics, particularly competition, will address the commenters' concerns about potential monopolies, appropriate costs for testing and certification, and the timely and efficient processing of requests for the testing and certification of Complete EHRs and EHR Modules. Guide 65 also requires ONC–ATCBs to make their services accessible to all applicants whose activities fall within its declared field of operation (*i.e.,* the temporary certification program), including not having any undue financial or other conditions. As noted throughout this rule, an ONC–ATCB must be in compliance with Guide 65 to remain in good standing under the temporary certification program.

Comments. One commenter requested that we only allow the testing and certification of open source Complete EHRs and EHR Modules under the temporary certification program and exclude proprietary Complete EHRs and EHR Modules. Commenters also inquired as to how we would test open source Complete EHRs and EHR Modules.

Response. We do not agree with the commenter that the temporary certification program should be limited to only open source Complete EHRs and EHR Modules. Proprietary Complete EHRs and EHR Modules will likely be widely purchased and/or utilized by the HIT market and we see no valid reason to exclude them from the temporary certification program. Open source Complete EHRs and EHR Modules will be tested and certified in the same manner as proprietary Complete EHRs and EHR Modules under the temporary certification program.

Comments. A few commenters expressed concern over the potential safety risks that could be associated with poorly planned, implemented, and used EHR technology and suggested that patient safety should be considered in the same context as the speed with which we develop and implement the temporary certification program.

Response. We understand and are acutely aware of the concerns expressed by the commenters regarding patient health and safety. We believe that the temporary certification program has been sufficiently constituted to ensure that ONC–ATCBs will competently test and certify Complete EHRs and EHR Modules. Further, we have established a process in the temporary certification program that the National Coordinator could use to immediately suspend an ONC–ATCB's ability to perform testing and certification if there is reliable evidence indicating that allowing an ONC–ATCB to continue its testing and certification processes would pose an adverse risk to patient health and safety.

Q. Comments Beyond the Scope of This Final Rule

In response to the Proposed Rule, some commenters chose to raise issues that are beyond the scope of our proposals. We do not summarize or respond to those comments in this final rule. However, we will review the comments and consider whether other actions may be necessary, such as addressing the comments in the permanent certification program's rulemaking or clarifying program operating procedures, based on the information or suggestions in the comments.

IV. Provisions of the Final Regulation

For the most part, this final rule incorporates the provisions of the Proposed Rule. Those provisions of this final rule that differ from the Proposed Rule are as follows:

- In § 170.401, we added "the requirements that ONC–ATCBs must follow to remain in good standing" to properly identify that this subpart contains requirements that ONC–ATCBs must follow to remain in good standing under the temporary certification program. This reference was inadvertently left out of the Proposed Rule.
- In § 170.402, we added the definitions of "development site," "deployment site," and "remote testing and certification."
- In § 170.405(b), we added "or ONC–ATCB" to clarify that either an applicant for ONC–ATCB status or an ONC–ATCB may, when necessary, utilize the specified correspondence methods. This reference was inadvertently left out of the Proposed Rule.
- In § 170.423, in response to public comments, we added a new Principle of Proper Conduct designated as paragraph (k). The new Principle of Proper Conduct will require ONC–ATCBs to ensure that all Complete EHRs and EHR Modules are properly identified and marketed.
- In § 170.423(e), we modified the language to require that ONC–ATCBs "[u]se test tools and test procedures approved by the National Coordinator for the purposes of assessing Complete EHRs and/or EHR Modules compliance with the certification criteria adopted by the Secretary."
- In § 170.423(h), we have specified that an ONC–ATCB will be additionally required to report the clinical quality measures to which a Complete EHR or EHR Module has been tested and certified and, where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary.
- In § 170.423(i), in response to comments, we made revisions to clarify that an ONC–ATCB must retain all records related to tests and certifications according to ISO Guide 65 and ISO 17025 for the duration of the temporary certification program and provide copies of the final results of all completed tests and certifications to ONC at the conclusion of testing and certification activities under the temporary certification program.
- In § 170.423(j), we made revisions to clarify that an ONC–ATCB will only

be responsible for issuing refunds in situations where the ONC–ATCB's conduct caused testing and certification to be suspended and a request for testing and certification is withdrawn, and in instances where the ONC–ATCB's conduct caused the testing and certification not to be completed or necessitated the recertification of Complete EHRs or EHR Modules it had previously certified.

• In § 170.430(a)(2), to provide clarity in response to public comments, we have stated that the National Coordinator will review each part of the application "in its entirety."

• In § 170.430(b)(1), we have removed the terms "inadvertent" and "minor" in response to public comment.

• In § 170.430(c), to respond to public comments, we have revised paragraph (c)(1) to allow an applicant for ONC–ATCB status to request an extension of the 15-day period provided to submit a revised application in response to a deficiency notice. We have revised paragraph (c)(2) to state that the National Coordinator can grant an applicant's request for an extension of the 15-day period based on a finding of good cause. We have also revised paragraph (c)(3) to permit the National Coordinator to request clarification of statements and the correction of errors or omissions in a revised application during the 15-day period that the National Coordinator has to review a revised application.

• In § 170.440(b), to respond to public comments, we have revised the paragraph to state, in relevant part, "Each ONC–ATCB must prominently and unambiguously identify the scope of its authorization on its Web site, and in all marketing and communications statements (written and oral) pertaining to its activities under the temporary certification program."

• In § 170.445(a), we revised the paragraph to state that "An ONC–ATCB must test and certify Complete EHRs to all applicable certification criteria adopted by the Secretary at subpart C of this part." This revision addresses public comments and ensures consistent requirements for ONC–ATCBs with regard to testing and certification requirements for Complete EHRs and EHR Modules. An ONC–ATCB must not just be capable of conducting the applicable testing and certification, but they are required to perform the appropriate testing and certification.

• In § 170.445, we re-designated paragraph (b) as paragraph (d). We then added a new provision, designated as paragraph (b), which states that an ONC–ATCB must provide the option for a Complete EHR to be tested and certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part. We also added another new provision, designated as paragraph (c), that requires an ONC–ATCB to accept requests for an updated version of a previously certified Complete EHR to inherit the previously certified Complete EHR issued certification without being retested and recertified.

• In § 170.450, we removed proposed paragraphs (b) and (d) because they are redundant of other regulatory requirements within this subpart. We then added a new provision, designated as paragraph (b), which states that an ONC–ATCB must provide the option for an EHR Module or a bundle of EHR Modules to be tested and certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part. We also added another new provision, designated as paragraph (d), that requires an ONC–ATCB to accept requests for an updated version of a previously certified EHR Module or bundle of EHR Modules to inherit the previously certified EHR Module or bundle of EHR Modules issued certification without being retested and recertified.

• In § 170.450(c), we revised the paragraph to state that EHR Modules shall be tested and certified to all privacy and security certification criteria adopted by the Secretary unless the EHR Module(s) is/are presented for testing and certification in one of the following manners: (1) The EHR Module(s) is/are presented for testing and certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR (as defined in 45 CFR 170.102), and one or more of the constituent EHR Modules is/are demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Module(s); or (2) An EHR Module is presented for testing and certification, and the presenter can demonstrate and provide documentation to the ONC–ATCB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be tested and certified in accordance with such certification criterion.

• In § 170.457, we revised the section to require that an ONC–ATCB provide remote testing and certification for both development and deployment sites.

• In § 170.465, we revised the section to provide the National Coordinator with the discretion to suspend an ONC–ATCB's operations if there is reliable evidence indicating that the ONC–ATCB has committed a Type-1 or Type-2 violation and that the continued testing and certification of Complete EHRs and/or EHR Modules by the ONC–ATCB could have an adverse impact on patient health or safety. An ONC–ATCB will have 3 days to respond to a notice of proposed suspension by explaining in writing why its operations should not be suspended. The National Coordinator will be permitted up to 5 days to review the response and issue a determination to the ONC–ATCB. The National Coordinator will make a determination to either rescind the proposed suspension, suspend the ONC–ATCB until it has adequately corrected a Type-2 violation, or propose revocation in accordance with § 170.465(c) and suspend the ONC–ATCB's operations for the duration of the revocation process. The National Coordinator may also make any one of the above determinations if an ONC–ATCB fails to submit a timely response to a notice of proposed suspension. A suspension will become effective upon an ONC–ATCB's receipt of a notice of suspension.

• In § 170.465(c)(1) we revised the provision to state that "[t]he National Coordinator may propose to revoke an ONC–ATCB's status if the National Coordinator has reliable evidence that the ONC–ATCB committed a Type-1 violation." The term "reliable" was inadvertently left out of the Proposed Rule.

• In § 170.490, we revised the section to state that the temporary certification program will sunset on December 31, 2011, or if the permanent certification program is not fully constituted at that time, then upon a subsequent date that is determined to be appropriate by the National Coordinator. We clarified that ONC–ATCBs will be prohibited from accepting new requests to test and certify Complete EHRs or EHR Modules "on and after the temporary certification program sunset date." We also revised the section to state that ONC–ATCBs are permitted up to six months after the sunset date to complete all testing and certification activities associated with requests for testing and certification of Complete EHRs and/or EHR Modules received prior to the sunset date.

• We added § 170.499 to incorporate by reference ISO/IEC Guide 65:1996 and ISO/IEC 17025:2005.

V. Technical Correction to § 170.100

We are making a technical correction to § 170.100. We inadvertently left out a citation to section 3001(c)(5) of the PHSA, which provides the statutory basis for the National Coordinator to establish certification program(s) for

HIT. We have revised § 170.100 to include reference to this statutory authority.

VI. Waiver of the 30-Day Delay in the Effective Date

We ordinarily provide a 30-day delay in the effective date of a final rule as required by section 553(d) of the Administrative Procedure Act (APA). 5 U.S.C. § 553(d). However, we can waive the 30-day delay in the effective date if the Secretary finds, for good cause, that the delay is impracticable, unnecessary, or contrary to the public interest, and includes a statement of the finding and the reasons in the rule issued. The Secretary finds that good cause exists to waive the 30-day delay in the effective date of this final rule. A delayed effective date would be contrary to the public interest because it would restrict the ability of eligible professionals and eligible hospitals to adopt and implement Certified EHR Technology.

As previously discussed, the HITECH Act provides incentive payments beginning in 2011 under the Medicare and Medicaid programs for eligible professionals and eligible hospitals that demonstrate meaningful use of Certified EHR Technology. The rules promulgated by ONC and CMS establish the regulatory framework through which eligible professionals and eligible hospitals may seek to qualify for those incentive payments. The Medicare and Medicaid EHR Incentive Programs proposed rule would establish meaningful use Stage 1 beginning in 2011. The HIT Standards and Certification Criteria interim final rule adopted certification criteria that directly support the proposed meaningful use Stage 1 objectives. This final rule establishes a temporary certification program that will allow Complete EHRs and EHR Modules to be tested and certified to the adopted certification criteria.

As a result, Certified EHR Technology will not be available to eligible professionals and eligible hospitals until the temporary certification program begins. Eligible professionals and eligible hospitals will need time to select, adopt, and implement Certified EHR Technology before they attempt to demonstrate meaningful use in 2011. In addition, before testing and certification can begin, ONC must review and deem satisfactory applications that are submitted by organizations that seek ONC–ATCB status. A delayed effective date for this final rule would delay the process for making Certified EHR Technology available to eligible professionals and eligible hospitals prior to the proposed beginning of meaningful use Stage 1 in 2011.

Several commenters voiced their strong concern that the temporary certification program needs to be established immediately so as to enable organizations to apply and be authorized to serve as ONC–ATCBs, to enable Complete EHR and EHR Module developers to have their Complete EHRs and/or EHR Modules certified, and to enable eligible professionals and eligible hospitals to obtain and implement Certified EHR Technology that will support their achievement of meaningful use. These commenters encouraged us to take immediate steps to issue this final rule and to permit organizations to apply for ONC–ATCB status. These commenters explained that it is necessary to have ONC–ATCBs in place as soon as possible in order for them to be positioned and prepared to test and certify Complete EHRs and EHR Modules in a timely manner.

For the reasons stated above, we believe that a delayed effective date for this final rule would be contrary to the public interest. Therefore, we find there is good cause to waive the 30-day delay in the effective date of this final rule.

VII. Collection of Information Requirements

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* the information collection included in this final rule has been submitted for emergency approval to OMB.

The two information collections specified under sections A and B below were previously published in the **Federal Register** as part of the Proposed Rule and HHS invited interested persons to submit comments on any aspect of each of the two information collections, including the following: (1) Necessity and utility of the information collection; (2) the accuracy of the estimate of the burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of collection without reducing the quality of the collected information.

The final rule contains one new information collection requirement pertaining to records retention and disclosure to ONC that was inadvertently left out of the Proposed Rule, but included in the emergency request to OMB. Please refer to section C below for this new information collection.

A. Collection of Information: Application for ONC–ATCB Status Under the Temporary Certification Program

Section 170.420 requires an applicant for ONC–ATCB status to submit to the National Coordinator a completed application. The application consists of two parts. Part 1 requires an applicant to submit general identifying information, complete self audits to Guide 65 and ISO 17025, and agree to adhere to the Principles of Proper Conduct for ONC–ATCBs. Part 2 requires an applicant to complete a proficiency examination. The proficiency examination is not, however, considered "information" for PRA collection purposes because it falls under the exception to the definition of information at 5 CFR 1320.3(h)(7). We estimated in the Proposed Rule that there would be no more than 3 applicants for ONC–ATCB status. We also assumed that these applicants would be familiar with the relevant requirements found in Guide 65 and ISO 17025 and would have a majority, if not all, of the documentation requested in the application already developed and available before applying for ONC–ATCB status. Therefore, with the exception of completing a proficiency examination, we concluded that an applicant would only spend time collecting and assembling already developed information to submit with their application. Based on these assumptions, we estimated that it would take approximately:

- 10 minutes for an applicant to provide the general identifying information requested in the application;
- 2 hours to complete the Guide 65 self audit and assemble associated documentation;
- 2 hours to complete the ISO 17025 self audit and assemble associated documentation; and
- 20 minutes to review and agree to the "Principles of Proper Conduct for ONC–ATCBs."

Comments. One commenter expressed a concern that we had underestimated the potential burden hours associated with applying for the temporary certification program. The commenter cited that while they had significant familiarity with testing and certification, their organization was not totally conformant to both Guide 65 and ISO 17025. The commenter stated that it had taken 120 hours to perform a gap analysis and that it would take approximately another several hundred more hours to properly conform to our

proposed requirements in order to be ready to apply for ONC–ATCB status.

Response. We agree with this commenter. As noted, we previously assumed and based on that assumption, estimated that applicants for ONC–ATCB status would already be conformant with Guide 65 and ISO 17025 and would have "in hand" the documentation we requested copies of as part of the ONC–ATCB application ("conformant applicants"). Given this commenter's analysis, we believe that it is reasonable to expect that one or two potential applicants for ONC–ATCB status ("partially conformant applicants") may need to perform more upfront work than other potential applicants. As a result, we have revised our estimates below to account for the fact that, at most, two potential applicants may need to perform more upfront work to prepare to apply for ONC–ATCB status and to account for the fact that we now anticipate that there may be up to five applicants for ONC–ATCB status.

In consultation with NIST, we believe that the 120 hours to perform a gap analysis is reasonable and have estimated that the remaining time it may take a potential applicant to become conformant with both Guide 65 and ISO 17025 would be a maximum of 280 hours. Thus, in order to be ready to apply for ONC–ATCB status, we believe that it will take approximately a maximum of 400 hours for a potential applicant to become conformant with Guide 65 and ISO 17025 and have equally distributed the burden among these two requirements. Our revised analysis is expressed in the table below.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Burden hours per response	Total burden hours
Conformant Applicant	ONC–ATCB Application	3	1	4.5	13.5
Partially Conformant Applicant	ONC–ATCB Application	2	1	400.5	801
Total					814.5

B. Collection of Information: ONC–ATCB Collection and Reporting of Information Related to Complete EHR and/or EHR Module Certifications

Section 170.423(h) requires an ONC–ATCB to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been tested and certified as well as certain minimum information about each certified Complete EHR and/or EHR Module.

We did not receive any comments on this collection of information. We have, however, specified in this final rule two additional reporting elements that must be submitted by ONC–ATCBs on a weekly basis (*i.e.,* clinical quality measures to which a Complete EHR or EHR Module has been tested and certified and, where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary). ONC–ATCBs will be capturing these additional reporting elements in conjunction with the other information we request that they report on a weekly basis. Consequently, we do not believe that the reporting of these two additional elements will increase the reporting burden for ONC–ATCBs.

Based on our new estimate that there may be up to 5 applicants that apply for ONC–ATCB status, we have revised our overall annual burden estimate. In doing so, we have maintained our prior assumptions. For the purposes of estimating the potential burden, we assume that all of the estimated applicants will apply and become ONC–ATCBs. We also assume that ONC–ATCBs will report weekly (*i.e.,* respondents will respond 52 times per year). Finally, we assume that the information collections will be accomplished through electronic data collection and storage, which will be part of the normal course of business for ONC–ATCBs. Therefore, with respect to this proposed collection of information, the estimated burden is limited to the actual electronic reporting of the information to ONC.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ONC–ATCB Testing and Certification Results	5	52	1	260

C. Collection of Information: ONC–ATCB Retention of Testing and Certification Records and the Submission of Copies of Records to ONC

Section 170.423(i) requires ONC–ATCBs to retain all records related to tests and certifications according to Guide 65 and ISO 17025 for the duration of the temporary certification program and provide copies of the final results of all completed tests and certifications to ONC at the conclusion of testing and certification activities under the temporary certification program.

We do not believe that there are any specific recordkeeping burdens associated with this requirement. Based on our consultations with NIST, we understand that it is standard industry practice to retain records related to testing and certification. Therefore, we believe that the only burden attributable to our requirement is associated with the submission of copies to ONC of the final results of all completed tests and certifications.

For the purposes of estimating the potential burden, we assume that all of the estimated number of applicants for the temporary certification program (*i.e.,* five) will become ONC–ATCBs. For calculation purposes, we also assume that each ONC–ATCB will incur the same burden. We assume that on average each ONC–ATCB will test and certify an equal amount of ONC's estimate of the maximum amount of

Complete EHRs and EHR Modules that will be tested and certified under the temporary certification program as specified in the regulatory impact analysis of this final rule. We estimate the equal amount of Complete EHRs and/or EHR Modules that will be tested and certified by each of the 5 estimated ONC–ATCBs to be approximately 205. Finally, we assume that an ONC–ATCB will submit copies of the final results of all completed tests and certifications to ONC by either electronic transmission or paper submission. In either instance, we believe that an ONC–ATCB will spend a similar amount of time and effort in organizing, categorizing and submitting the requested information. We estimate that this amount of time will be approximately 8 hours for each ONC–ATCB. Our estimates are expressed in the table below.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ONC–ATCB Testing and Certification Records	5	1	8	40

VIII. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). Based on the analysis of costs and benefits that follows, we have determined that this final rule covering the temporary certification program is not an economically significant rule because we estimate that the overall costs and benefits associated with the temporary certification program, including the costs associated with the testing and certification of Complete EHRs and EHR Modules, to be less than $100 million per year. Nevertheless, because of the public interest in this final rule, we have prepared an RIA that to the best of our ability presents the costs and benefits of the final rule.

B. Why is this rule needed?

As stated in earlier sections of this final rule, section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of HIT. This final rule is needed to outline the processes by which the National Coordinator would exercise this authority to authorize certain organizations to test and certify Complete EHRs and/or EHR Modules. Once certified, Complete EHRs and EHR Modules will be able to be used by eligible professionals and eligible hospitals as, or be combined to create, Certified EHR Technology. Eligible professionals and eligible hospitals who seek to qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs are required by statute to use Certified EHR Technology.

C. Executive Order 12866—Regulatory Planning and Review Analysis

1. Comment and Response

Comments. A few commenters expressed concerns that the costs we attributed in the Proposed Rule related to the testing and certification of Complete EHRs and EHR Modules were too high, unrealistic, and unreliable. One commenter requested that we remove our cost estimates because they believed they were based on a monopolistic pricing structure. Other commenters indicated that we should regulate the pricing related to testing and certification in order to ensure that prices were not exorbitant and did not preclude smaller Complete EHR and EHR Module developers from being able to attain certification for their product.

Response. We understand the commenters' concerns; however, we have a responsibility to put forth a good faith effort to estimate the potential costs associated with this final rule. Part of that effort includes using the best available data to inform our assumptions and estimates. While we were open to revising our cost estimates in response to public comment, in no instance did a commenter provide alternative estimates or reference additional information from which we could base revisions. Conversely, we believe that commenters who expressed concerns about the potential costs, largely did so from the perspective of stating a request that we ensure the costs for testing and certification were not prohibitively high.

While we understand these commenters' perspectives, we do not believe that it is appropriate to dictate the minimum or maximum amount an ONC–ATCB should be able to charge for testing and certifying a Complete EHR or EHR Module. However, as evidenced by the increase in our estimate of the number of ONC–ATCB applicants under the temporary certification program, it is our hope that multiple ONC–ATCBs will be authorized and will compete for market share. As a result of expected increased competition among ONC–ATCBs, we believe there could also be increased downward pressure on the costs associated with testing and certification. If that cost pressure occurs, we believe that the upper ranges of the cost estimates we provide in this final rule could be overestimates.

Comments. Some commenters questioned our estimates related to the number of EHR Modules we expected to be tested and certified. One commenter suggested that the number of self-developed EHR Modules should be much higher than we estimated. Other commenters expressed that this rule needed to account for other costs associated with testing and certification (*e.g.,* reprogramming a Complete EHR or EHR Module) and not just the costs associated with the application process and for Complete EHRs and EHR Modules to be tested and certified.

Response. This final rule is one of three coordinated rulemakings. Each of these rulemakings accounts for its specific effects. In the HIT Standards and Certification *Criteria interim final rule (75 FR 2038), we summarized these effects as follows:*

While there is no bright line that divides the effects of this interim final rule and the other two noted above, we believe that each analysis properly focuses on the direct effects of the provisions it creates. This interim final rule estimates the costs commercial vendors, open source developers, and relevant Federal agencies will incur to prepare Complete EHRs and EHR Modules to be tested and certified to adopted standards, implementation specifications, and certification criteria. The Medicare and Medicaid EHR Incentive Programs proposed rule estimates the impacts related to the actions taken by eligible professionals or eligible hospitals to become meaningful users, including purchasing or self-developing Complete EHRs or EHR Modules. The HIT Certification Programs proposed rule estimates the testing and certification costs for Complete EHRs and EHR Modules.

As result, we estimate in this final rule, as we had before, the effects of the application process for ONC–ATCB status and the costs for Complete EHRs and EHR Modules to be tested and certified by ONC–ATCBs. With respect to EHR Modules, especially self-developed EHR Modules, we agree with those commenters regarding our estimates and have provided revised estimates that factor in a potential larger number of self-developed EHR Modules. While neither commenter who offered this concern related to EHR Modules provided any data to substantiate their claims, we determined that this revision was necessary because we had previously grouped self-developed Complete EHRs and EHR Modules together. Upon further review and other comments addressed above regarding EHR Modules, we believe that in order to provide a more accurate estimate, self-developed Complete EHRs and EHR Modules should be separately accounted for. We believe our prior estimates related to self-developed Complete EHRs and EHR Modules are more appropriately attributable to the number of self-developed Complete EHRs. Accordingly, we have developed new estimates (captured in the discussion and tables below) for the number of self-developed EHR Modules that we believe will be presented for testing and certification.

2. Executive Order 12866 Final Analysis

As required by Executive Order 12866, we have examined the economic implications of this rule as it relates to the temporary certification program. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a regulation as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million, or in a material way adversely affecting the economy, a sector of the economy, competition, or jobs. While this rule is therefore not "economically significant," as defined by Executive Order 12866, OMB has determined that this rule constitutes a "significant regulatory action" as defined by Executive Order 12866 because it raises novel legal and policy issues.

a. Temporary Certification Program Estimated Costs

i . Application Process for ONC–ATCB Status

Applicant Costs

As discussed under the collection of information section, we have increased our estimate of the number of applicants we expect will apply for ONC–ATCB status. In the Proposed Rule, we stated that we anticipated that there would be no more than 3 applicants for ONC–ATCB status. Based on the comments received, we now believe that there may be up to 5 applicants for ONC–ATCB status. In addition, we believe that up to 2 of these applicants will not have the level of preparedness that we originally estimated for all potential applicants for ONC–ATCB status.

As part of the temporary certification program, an applicant will be required to submit an application and complete a proficiency exam. We do not believe that there will be an appreciable difference in the time commitment an applicant for ONC–ATCB status will have to make based on the type of authorization it seeks (*i.e.,* we believe the application process and time commitment will be the same for applicants seeking authorization to conduct the testing and certification of either Complete EHRs or EHR Modules). We do, however, believe that there will be a distinction between applicants based on their level of preparedness. For the purposes of estimating applicant costs, we have divided applicants into two categories, "conformant applicants" and "partially conformant applicants." We still believe, after reviewing comments, that there will be three "conformant applicants" and that these applicants will have reviewed the relevant requirements found in the ISO/IEC standards and will have a majority, if not all, of the documentation requested in the application already developed and available before applying for ONC–ATCB status. Therefore, with the exception of completing a proficiency examination, we believe "conformant applicants" will only spend time collecting and assembling already developed information to submit with their application. Conversely, we believe that there will be up to two "partially conformant applicants" and that these applicants will spend significantly more time establishing their compliance with Guide 65 and ISO 17025. Based on our assumptions, review of comments, and consultations with NIST, we anticipate that it will take a "conformant applicant" approximately 28.5 hours and a "partially conformant applicant" approximately 424.5 hours to complete the application and submit the requested documentation. Our estimates include the time discussed above in our collection of information section and approximately up to 24 hours for all applicants to complete the proficiency examination—8 hours (1 full work day) to complete section 1 (demonstration of technical expertise related to Complete EHRs and/or EHR Modules); 6 hours to complete section 2 (demonstration of test tool identification); and 10 hours to complete section 3 (demonstration of proper use of test tools and understanding of test results). Moreover, after consulting with NIST we assume that:

- An employee equivalent to the Federal Salary Classification of GS–9 Step 1 could provide the general information requested in the application and accomplish the paperwork duties associated with the application;
- An employee equivalent to the Federal Salary Classification of GS–15 Step 1 would be responsible for conducting the self audits and agreeing to the "Principles of Proper Conduct for ONC–ATCBs"; and
- An employee or employees equivalent to the Federal Salary Classification of GS–15 Step 1 would be responsible for completing the proficiency examination.

We have taken these employee assumptions and utilized the corresponding employee hourly rates for the locality pay area of Washington, D.C. as published by the U.S. Office of Personnel Management (OPM), to calculate our cost estimates. We have also calculated the costs of an employee's benefits while completing the application. We have calculated these costs by assuming that an applicant expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. We have concluded that a 36% expenditure on benefits is an appropriate estimate

because it is the routine percentage used by HHS for contract cost estimates. Our calculations are expressed in Tables 1 and 2 below.

TABLE 1—TEMPORARY CERTIFICATION PROGRAM: COST TO APPLICANTS TO APPLY TO BECOME AN ONC–ATCB

Application requirement	Employee equivalent	Burden hours		Employee hourly wage rate	Cost of employee benefits per hour	Cost per applicant	
		Conformant applicant	Partially conformant applicant			Conformant applicant	Partially conformant applicant
General Identifying Information.	GS–9 Step 1 ..	10/60	10/60	$22.39	$8.06	$5.07	$5.07
Self Audits and Documentation.	GS–15 Step 1	4	400	59.30	21.35	322.60	32,260.00
Principles of Proper Conduct.	GS–15 Step 1	20/60	20/60	59.30	21.35	26.89	26.89
Proficiency Examination.	GS–15 Step 1	24	24	59.30	21.35	1,935.60	1,935.60
Total Cost Per Application.	.....	.....	.....	.....	.....	$2,290.16	$34,227.56

TABLE 2—TEMPORARY CERTIFICATION PROGRAM: TOTAL APPLICANT COST

Type of applicant	Anticipated number of applicants	Cost of application per applicant ($)	Total cost estimate ($)
Conformant Applicant	3	$2,290.16	$6,870.48
Partially Conformant Applicant	2	34,227.56	68,455.12
Total Cost of Application Process	.....	.....	75,325.60

We based our cost estimates on the amount of applicants that we believe will apply over the life of the temporary certification program. We assume that all applicants will apply during the first year of the program and thus all application costs should be attributed to the first year of the program. However, based on our projection that the temporary certification program will last approximately two years and that one or two applicants may choose to apply in the second year, the annualized cost of the application process will be $37,663.

Costs to the Federal Government

We have estimated the cost to develop the ONC–ATCB application, including the development and administration of the proficiency examination to be $34,618 based on the 495 hours we believe it will take to develop the application, prepare standard operating procedures as well as create the requisite pools of questions for the proficiency examinations. More specifically, we believe it will take 360 hours of work of a Federal Salary Classification GS–14 Step 1 employee located in Washington, DC to develop the proficiency examination, 80 hours of work by the same employee to develop the standard operation procedures and the actual application, and 55 hours to score all the exams and handle related administrative tasks.

We also anticipate that there will be costs associated with reviewing applications under the temporary certification program. We expect that a GS–15 Step 1 employee will review the applications and the National Coordinator (or designated representative) will issue final decisions on all applications. We anticipate that it will take approximately 40 hours to review and reach a final decision on each application. This estimate assumes a satisfactory application (*i.e.,* no formal deficiency notifications) and includes the time necessary to verify the information in each application, assess the results of the proficiency examination, and prepare a briefing for the National Coordinator. We estimate the cost for the application review process, which we anticipate will include the review of 5 applications, to be $16,900.

As a result, we estimate the Federal government's overall cost of administering the entire application process, for the length of the temporary certification program, at approximately $51,518. Based on our projection that the temporary certification program will last approximately two years and that one or two applicants may choose to apply in the second year, the annualized cost to the Federal government for administering the entire application process will be $25,759.

As previously noted, we will also post the names of applicants granted ONC–ATCB status on our Web site. We believe that there will be minimal cost associated with this action and have calculated the potential cost to be approximately $260 on an annual basis for posting and maintaining the information on our Web site (a maximum of 5 hours of work for a Federal Salary Classification GS–12 Step 1 employee located in Washington, DC).

ii. Testing and Certification of Complete EHRs and EHR Modules

Section 3001(c)(5)(A) of the PHSA indicates that certification is a voluntary act; however, due to the fact that the Medicare and Medicaid EHR Incentive Programs require eligible professionals and eligible hospitals to use Certified EHR Technology in order to qualify for incentive payments, we anticipate that a significant portion of Complete EHR and EHR Module developers will seek to have their HIT tested and certified.

In Tables 3 through 8 below, we estimate the costs for Complete EHRs and EHR Modules to be tested and certified under the temporary certification program. As discussed in the HIT Standards and Certification Criteria interim final rule, and to remain consistent with our previous estimates (75 FR 2039), we believe that

approximately 93 commercial/open source Complete EHRs and 50 EHR Modules will be tested and certified under our proposed temporary certification program. In addition to these costs, we also take into account what we believe will be the costs incurred by a percentage of eligible professionals and eligible hospitals who themselves will incur the costs associated with the testing and certification of their self-developed Complete EHR or EHR Module(s).

With respect to the potential for eligible professionals to seek testing and certification for a self-developed Complete EHR, DesRoches found that only 5% of physicians are in large practices of over 50 doctors.[3] Of these large practices, 17% use an "advanced EHR system" that could potentially be tested and certified if it were self-developed (we assume that smaller physician practices do not have the resources to self-develop a Complete EHR). We are unaware of any reliable data on the number of large practices who may have a self-developed Complete EHR for which they would seek to be tested and certified. As a result, we offer the following estimate based on currently available data. We believe that the total number of eligible professionals in large practices who both possess an IT staff with the resources to develop and support a Complete EHR and would seek to have such a self-developed Complete EHR tested and certified will be low—no more than 10%. By taking CMS's estimate in its proposed rule of approximately 450,000 eligible professionals (75 FR 1960) we multiply through by the numbers above (450,000 $\times$ .05 $\times$ .17 $\times$ .10) and then divide by a practice size of at least 50 which yields approximately 8 self-developed Complete EHRs designed for an ambulatory setting that could be submitted for testing and certification. Additionally, we believe that a reasonable estimate for the number of large practices with the IT staff and resources to self-develop an EHR Module and that would seek to have such an EHR Module tested and certified can also be derived from the calculation above but with a few differences. We start with the total number of large practices from the calculation above (~77). We then assume an average number (1.1) of self-developed EHR Modules for this group of large practices and further refine this estimate by providing low and high probability assumptions (10% and 70%, respectively) to represent the likelihood that any one of these large practices possess a self-developed EHR Module that they would seek to have tested and certified. Given that no commenter provided data to further support this estimate, we believe that our maximum number of self-developed EHR Modules estimate is generous. While we do not dispute that practice sizes smaller than 50 could also possess self-developed EHR Modules, we believe those smaller practices will be the exception, not the rule, and that separately calculating a total for these smaller practices would produce a negligible amount of EHR Modules to add to our overall range.

With respect to eligible hospitals, similar to eligible professionals, we believe that only large eligible hospitals would have the IT staff and resources available to possess a self-developed Complete EHR that they would seek to have tested and certified. Again, we are unaware of any reliable data on the number of eligible hospitals who may have a self-developed Complete EHR for which they would seek to be tested and certified. Further, we believe that with respect to EHR Modules the probability varies across different types of eligible hospitals regarding their IT staff resources and ability to self-develop an EHR Module and seek to have it tested and certified. As a result, we offer the following estimates based on currently available data. We have based our calculations on the Medicare eligible hospital table CMS provided in its proposed rule (Table 38) (75 FR 1980) which conveys hospital IT capabilities according to three levels of adoption by hospital size according to the 2007 AHA annual survey. These three levels included: (1) Hospitals which had already implemented relatively advanced systems that included CPOE systems for medications; (2) hospitals which had implemented more basic systems through which lab results could be shared, but not CPOE for medications; and (3) hospitals starting from a base level either CPOE or lab reporting. CMS indicated that CPOE for medication standard was chosen because expert input indicated that the CPOE standard in the proposed meaningful use definition will be the hardest one for hospitals to meet.

As stated above, we believe that only large hospitals (defined in Table 38 as those with 400+ beds) would have the IT staff and resources to develop, support, and seek the testing and certification of a self-developed Complete EHR. CMS indicated that 331 large hospitals had met either "level 1" or "level 2." As a result, we estimate that approximately 10% of these large eligible hospitals have a self-developed Complete EHR and would seek to have it tested and certified. We believe that this estimate is generous and that a good portion of the eligible professionals and eligible hospitals who would likely seek to qualify for incentive payments with self-developed Complete EHRs would only do so for meaningful use Stage 1. After meaningful use Stage 1 we anticipate that the number of eligible professionals and eligible hospitals who would incur the costs of testing and certification themselves will go down because the effort involved to maintain a Complete EHR may be time and cost prohibitive as the Secretary continues to adopt additional certification criteria to support future stages of meaningful use.

With respect to self-developed EHR Modules, we believe the probability varies across different types of eligible hospitals (CAHs, Small/Medium, and Large) regarding their IT staff resources and ability to self-develop EHR Modules. For each hospital type (identified in Table 38) we provide an estimate of the average number of self-developed EHR Modules we believe each type of eligible hospital would seek to have tested and certified. Again, we believe that our high average number of self-developed EHR Modules is generous.

Due to the fact that an ONC–ATCB will be responsible for testing and certifying Complete EHRs and/or EHR Modules, we have combined the costs for testing and certification because we believe they would be difficult to independently estimate. Our cost range for the testing and certification of Complete EHRs and EHR Modules includes consideration of how the testing and certification will be conducted (*i.e.,* by remote testing and certification, on-site testing and certification, or at the ONC–ATCB and for the complexity of an EHR Module).

On July 14, 2009, CCHIT testified in front of the HIT Policy Committee on the topic of EHR certification, including the certification of EHR Modules. CCHIT estimated that "EHR-comprehensive" according to CCHIT certification criteria would have testing and certification costs that would range from approximately $30,000 to $50,000. CCHIT also estimated that the testing and certification of EHR Modules would range from approximately $5,000 to $35,000 depending on the scope of the testing and certification. We believe that these estimates provide a reasonable foundation and have used them for our cost estimates. However, we assume that competition in the testing and

[3] DesRoches, CM *et al.* Electronic Health Records in Ambulatory Care—A National Survey of Physicians, New England Journal of Medicine July 2008; 359:50–60.

certification market will reduce the costs of testing and certification as estimated by CCHIT but we are unable to provide a reliable estimate at this time of what the potential reduction in costs might be. The following tables represent our cost estimates for the preceding discussion and include:

- Commercial/Open Source Complete EHRs and EHR Modules—Table 3;
- Self-developed Complete EHRs—Table 4;
- Number of Self-developed EHR Modules by eligible professionals in large practices—Table 5;
- Number of Self-developed EHR Modules by type of eligible hospital—Table 6; and
- Total costs associated with self-developed EHR Modules—Table 7.

TABLE 3—TEMPORARY CERTIFICATION PROGRAM: ESTIMATED COSTS FOR TESTING & CERTIFICATION OF COMMERCIAL/OPEN SOURCE COMPLETE EHRS AND EHR MODULES

Type	Number tested and certified	Cost per complete EHR/EHR module ($M)			Total cost for all complete EHRs/EHR modules over 3-year period ($M)		
		Low	High	Mid-point	Low	High	Mid-point
Complete EHR	93	$0.03	$0.05	$0.04	$2.79	$4.65	$3.72
EHR Module	50	0.005	0.035	0.02	0.25	1.75	1.0
Total	143				3.04	6.4	4.72

TABLE 4—TEMPORARY CERTIFICATION PROGRAM: ESTIMATED COSTS FOR TESTING & CERTIFICATION OF SELF-DEVELOPED COMPLETE EHRS

Type	Number tested and certified	Cost per complete EHR ($M)			Total cost for all complete EHRs over 3-year period ($M)		
		Low	High	Mid-point	Low	High	Mid-point
Self Developed Complete EHRs Ambulatory Setting	8	$0.03	$0.05	$0.04	$0.24	$0.4	$0.32
Self-Developed Complete EHRs Inpatient Setting	30	0.03	0.05	0.04	0.9	1.5	1.2
Total	38				1.14	1.9	1.52

In Table 5 below, we provide our estimate for the number of potential self-developed EHR Modules large practices of eligible professionals could seek to have tested and certified.

TABLE 5—TEMPORARY CERTIFICATION PROGRAM: ESTIMATED NUMBER OF SELF-DEVELOPED EHR MODULES DESIGNED FOR AN AMBULATORY SETTING BY ELIGIBLE PROFESSIONALS IN LARGE PRACTICES

Eligible professional practice type	Number of large practices	% with EHR module (low)	% with EHR module (high)	Average number of EHR modules, if any	Min number of EHR modules	Max number EHR modules
Large	77	10	70	1.25	10	67

In Table 6 below, we provide our estimate for the number of potential self-developed EHR Modules varied by hospital type that eligible hospitals could seek to have tested and certified.

TABLE 6—TEMPORARY CERTIFICATION PROGRAM: ESTIMATED NUMBER OF SELF-DEVELOPED EHR MODULES DESIGNED FOR AN INPATIENT SETTING STRATIFIED BY TYPE OF ELIGIBLE HOSPITAL

Type of eligible hospital	Number of EHs	% with EHR module (low)	% with EHR module (high)	Average number of EHR modules, if any	Min number of EHR modules	Max number EHR modules
CAH	518	1	10	1.1	6	57
S/M	1951	5	15	1.5	146	439
Large	331	25	70	2.0	166	463
Total	2800				318	959

In Table 7 below, we provide our estimate for the total testing and certification costs associated with the minimum and maximum number of self-developed EHR Modules from Table 5 and Table 6.

TABLE 7—TEMPORARY CERTIFICATION PROGRAM: ESTIMATED COSTS FOR TESTING & CERTIFICATION OF ALL SELF-DEVELOPED EHR MODULES

Self-developed EHR modules	Number tested and certified	Cost per EHR module ($M)			Total cost for all EHR modules over 3-year period ($M)		
		Low	High	Mid-point	Low	High	Mid-point
Min No. of EHR Modules	328	$0.005	$0.035	$0.02	$1.64	$11.5	$6.56
Max No. of EHR Modules	1026	0.005	0.035	0.02	5.13	35.9	20.52
Total					6.77	47.4	27.1

Our estimates cover anticipated testing and certification costs under the temporary certification program from 2010 through some portion of 2012 as we expect the permanent certification program to be operational by 2012. However, because we cannot predict the exact date at which ONC–ATCBs will finish any remaining tests and certifications in their queue, we believe that it is reasonable to assume the possibility that 2012 costs for testing and certification could be considered as part of the temporary certification program.

Consistent with our estimates in the HIT Standards and Certification Criteria interim final rule (75 FR 2041) about when Complete EHRs and EHR Modules will be prepared for testing and certification to the certification criteria adopted by the Secretary for meaningful use Stage 1, we anticipate that they will be tested and certified in the same proportions. Therefore, we believe that of the total number of Complete EHRs and EHR Modules that we have estimated (commercial, open source, and self-developed), 45% will be tested and certified in 2010, 40% will be tested and certified in 2011, and 15% will be tested and certified in 2012. Table 8 below represents this proportional distribution of the estimated costs we calculated for the testing and certification of Complete EHRs and EHR Modules to the certification criteria adopted to support meaningful use Stage 1 under the temporary certification program as expressed in Table 3 above.

TABLE 8—DISTRIBUTED TOTAL COSTS FOR THE TESTING AND CERTIFICATION OF COMPLETE EHRS AND EHR MODULES TO STAGE 1 MU BY YEAR (3-YEAR PERIOD)—TOTALS ROUNDED

Year	Ratio	Total low cost estimate ($M)	Total high cost estimate ($M)	Total average cost estimate ($M)
2010	45%	$4.93	$25.07	$15.00
2011	40%	4.38	22.28	13.34
2012	15%	1.64	8.36	5.00
3-Year Totals		10.95	55.7	33.34

iii. Costs for Collecting, Storing, and Reporting Certification Results

Costs to ONC–ATCBs

Under the temporary certification program, ONC–ATCBs will be required to provide ONC, no less frequently than weekly, an up-to-date list of Complete EHRs and/or EHR Modules that have been tested and certified as well as certain minimum information about each certified Complete EHR and/or EHR Module.

As stated in the collection of information section, we will require the reporting of this information on a weekly basis and that it will take ONC–ATCBs about an hour to prepare and electronically transmit the information to ONC each week (*i.e.,* respondents will respond 52 times per year). As also noted in the collection of information section, we have specified in this final rule two additional reporting elements that must be submitted by ONC–ATCBs on a weekly basis (*i.e.,* clinical quality measures to which a Complete EHR or EHR Module has been tested and certified and, where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary). ONC–ATCBs will be capturing these additional reporting elements in conjunction with the other information we request that they report on a weekly basis. Consequently, we do not believe that the reporting of these two additional elements will increase the reporting burden or costs for ONC–ATCBs.

We believe that an employee equivalent to the Federal Classification of GS–9 Step 1 could complete the transmissions of the requested information to ONC. We have utilized the corresponding employee hourly rate for the locality pay area of Washington, D.C., as published by OPM, to calculate our cost estimates. We have also calculated the costs of the employee's benefits while completing the transmissions of the requested information. We have calculated these costs by assuming that an ONC–ATCB or ONC–ACB expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. We have concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our cost estimates are expressed in Table 9 below.

TABLE 9—ANNUAL COSTS FOR AN ONC–ATCB TO REPORT CERTIFICATIONS TO ONC

Program requirement	Employee equivalent	Annual burden hours per ONC–ATCB	Employee hourly wage rate	Employee benefits hourly cost	Total cost per ONC–ATCB
ONC–ATCB Certification Results	GS–9 Step 1	52	$22.39	$8.06	$1,583.40

To estimate the highest possible cost, we assume that all of the estimated applicants (*i.e.,* five) that we anticipate will apply under the temporary certification program will become ONC–ATCBs. Therefore, we estimate the total annual reporting cost under the temporary certification program to be $7,917.

We believe that the requirement for ONC–ATCBs to retain certification records for the length of the temporary certification program is in line with common industry practices and, consequently, does not represent additional costs to ONC–ATCBs as a result of this final rule.

Costs to the Federal Government

As stated previously in this final rule, we will post a comprehensive list of all certified Complete EHRs and EHR Modules on our Web site. We believe that there will be minimal cost associated with this action and have calculated the potential cost, including weekly updates, to be $8,969 on an annualized basis. This amount is based on 173 hours of yearly work of a Federal Salary Classification GS–12 Step 1 employee located in Washington, DC.

iv. Costs for Retaining Records and Providing Copies to ONC

Costs to ONC–ATCBs

Under the temporary certification program, ONC–ATCBs will be required to retain all records related to tests and certifications according to Guide 65 and ISO 17025 for the duration of the temporary certification program and provide copies of the final results of all completed tests and certifications to ONC at the conclusion of testing and certification activities under the temporary certification program.

We do not believe that there are any specific recordkeeping or capital costs associated with this requirement. Based on our consultations with NIST, we understand that it is standard industry practice to retain records related to testing and certification. Therefore, we believe that the only costs attributable to our requirement are those associated with the submission of copies to ONC of the final results of all completed tests and certifications.

As stated in the collection of information section, we estimate that each ONC–ATCB will incur the same burden and, assuming that there are 5 ONC–ATCBs, will test and certify, at most, approximately 205 Complete EHRs and/or EHR Modules under the temporary certification program. We also assume that an ONC–ATCB will submit copies of the final results of all completed tests and certifications to ONC by either electronic transmission or paper submission. In either instance, we believe that an ONC–ATCB will spend a similar amount of time and effort in organizing, categorizing and submitting the requested information. We estimate that this amount of time will be approximately 8 hours for each ONC–ATCB.

Based on our own assumptions and consultations with NIST, we believe that an employee equivalent to the Federal Classification of GS–9 Step 1 could organize, categorize, and submit the final results of all completed tests and certifications either by electronic transmission or through paper submission of photocopies to ONC. We have taken this employee assumption and utilized the corresponding employee hourly rate for the locality pay area of Washington, DC, as published by the U.S. Office of Personnel Management, to calculate the cost estimates. We have also calculated the costs of the employee's benefits while organizing, categorizing, and submitting the final results. We have calculated these costs by assuming that an ONC–ATCB will expend thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. We have concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our calculations are expressed in the table below.

TABLE 10—COSTS FOR AN ONC–ATCB TO SUBMIT COPIES OF RECORDS TO ONC

Program requirement	Employee equivalent	Burden hours per ONC–ATCB	Employee hourly wage rate	Employee benefits hourly cost	Total cost per ONC–ATCB
Submission of Testing and Certification Records	GS–9 Step 1	8	$22.39	$8.06	$243.60

To estimate the highest possible cost, we assume that all of the estimated applicants (*i.e.,* five) that we anticipate will apply under the temporary certification program will become ONC–ATCBs. Therefore, we estimate the total cost for submitting the requested records at the conclusion of testing and certification activities under the temporary certification program to be $1,218.00.

Costs to the Federal Government

We anticipate that ONC will simply receive copies of the final results of all completed tests and certifications. Therefore, we believe the Federal government will only incur negligible costs.

b. Temporary Certification Program Benefits

We believe that several benefits will accrue from the establishment of the temporary certification program. The temporary certification program will allow for the rapid influx of Complete EHRs and EHR Modules to be tested and certified at a sufficient pace for eligible professionals and eligible hospitals to adopt and implement Certified EHR Technology for meaningful use Stage 1 and thus potentially qualify for incentive payments under the CMS Medicare and Medicaid EHR Incentive Programs proposed rule. The time between the temporary certification program and the permanent certification

program will permit the HIT industry the time it needs for accredited testing laboratories to come forward, for an ONC-authorized accreditor to be approved and for additional applicants for ONC–ACB status to come forward. We further believe that the temporary certification program will meet our overall goals of accelerating health IT adoption and increasing levels of interoperability. At this time, we cannot predict how fast all of these savings will occur or their precise magnitude as they are partly dependent on future final rules for meaningful use and the subsequent standards and certification criteria adopted by the Secretary.

D. Regulatory Flexibility Act

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For more information on the Small Business Administration's (SBA's) size standards, see the SBA's Web site.[4] For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. When conducting a RFA we are required to assess the potential effects of our rule on small entities and to make every effort to minimize the regulatory burden that might be imposed on small entities. We believe that the entities that are likely to be directly affected by this final rule are applicants for ONC–ATCB status. Furthermore, we believe that these entities would either be classified under the North American Industry Classification System (NAICS) codes 541380 (Testing Laboratories) or 541990 (Professional, Scientific and Technical Services).[5] We believe that there will be up to 5 applicants for ONC–ATCB status. According to the NAICS codes identified above, this would mean SBA size standards of $12 million and $7 million in annual receipts, respectively.[6] Because this segment of the HIT industry is in a nascent stage and is comprised of very few entities, we have been unable to find reliable data from which to determine what realistic annual receipts would be. However, based on our total estimates for Complete EHRs and EHR Modules to be tested and certified, we assume that the annual receipts of any one ONC–ATCB could be in the low millions of dollars. Moreover, it is unclear, whether these entities may be involved in other testing and certification programs which would increase their annual receipts and potentially place them outside the SBA's size standards.

We believe that we have established the minimum amount of requirements necessary to accomplish our policy goals and that no appropriate regulatory alternatives could be developed to lessen the compliance burden for applicants for ONC–ATCB status as well as ONC–ATCBs once they have been granted such status by the National Coordinator. Moreover, we believe that this final rule will create direct positive effects for entities because their attainment of ONC–ATCB status will permit them to test and certify Complete EHRs and/or EHR Modules. Thus, we expect that their annual receipts will increase as a result of becoming an ONC–ATCB.

We did not receive any comments related to our RFA analysis during the comment period available for the temporary certification program. As a result, we examined the economic implications of this final rule and have concluded that it will not have a significant impact on a substantial number of small entities. The Secretary certifies that this final rule will not have a significant impact on a substantial number of small entities.

E. Executive Order 13132—Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications.

Nothing in this final rule imposes substantial direct requirement costs on State and local governments, preempts State law or otherwise has federalism implications. We are not aware of any State laws or regulations that conflict with or are impeded by our temporary certification program, and we did not receive any comments to the contrary in response to the Proposed Rule.

F. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires cost-benefit and other analyses before any rulemaking if the rule includes a "Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." The current inflation-adjusted statutory threshold is approximately $133 million. We did not receive any comments related to the temporary certification program on our analysis presented in the Proposed Rule. Therefore, we have determined that this final rule will not constitute a significant rule under the Unfunded Mandates Reform Act, because it imposes no mandates.

OMB reviewed this final rule.

List of Subjects in 45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

■ For the reasons set forth in the preamble, 45 CFR subtitle A, subchapter D, part 170, is amended as follows:

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 1. The authority citation for part 170 is revised to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C 300jj–14; 5 U.S.C. 552.

■ 2. Revise § 170.100 to read as follows:

§ 170.100 [Amended]

The provisions of this subchapter implement sections 3001(c)(5) and 3004 of the Public Health Service Act.

■ 3. In § 170.102, add in alphabetical order the definition of "Day or Day(s)" to read as follows:

§ 170.102 Definitions.

* * * * *

Day or Days means a calendar day or calendar days.

* * * * *

■ 4. Add a new subpart D to part 170 to read as follows:

Subpart D—Temporary Certification Program for HIT

Sec.

170.400 Basis and scope.
170.401 Applicability.
170.402 Definitions.
170.405 Correspondence.
170.410 Types of testing and certification.
170.415 Application prerequisite.
170.420 Application.
170.423 Principles of proper conduct for ONC–ATCBs.

[4] *http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf.*

[5] *See* 13 CFR 121.201

[6] The SBA references that annual receipts means "total income" (or in the case of a sole proprietorship, "gross income") plus "cost of goods sold" as these terms are defined and reported on Internal Revenue Service tax return forms. *http://www.sba.gov/idc/groups/public/documents/sba_homepage/guide_to_size_standards.pdf.*

170.425 Application submission.
170.430 Review of application.
170.435 ONC–ATCB application reconsideration.
170.440 ONC–ATCB status.
170.445 Complete EHR testing and certification.
170.450 EHR Module testing and certification.
170.455 Testing and certification to newer versions of certain standards.
170.457 Authorized testing and certification methods.
170.460 Good standing as an ONC–ATCB.
170.465 Revocation of authorized testing and certification body status.
170.470 Effect of revocation on the certifications issued to complete EHRs and EHR Modules.
170.490 Sunset of the temporary certification program.
170.499 Incorporation by reference.

Subpart D—Temporary Certification Program for HIT

§ 170.400 Basis and scope.

This subpart implements section 3001(c)(5) of the Public Health Service Act, and sets forth the rules and procedures related to the temporary certification program for health information technology administered by the National Coordinator for Health Information Technology.

§ 170.401 Applicability.

This subpart establishes the processes that applicants for ONC–ATCB status must follow to be granted ONC–ATCB status by the National Coordinator, the processes the National Coordinator will follow when assessing applicants and granting ONC–ATCB status, the requirements that ONC–ATCBs must follow to remain in good standing, and the requirements of ONC–ATCBs for testing and certifying Complete EHRs and/or EHR Modules in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part.

§ 170.402 Definitions.

For the purposes of this subpart:

Applicant means a single organization or a consortium of organizations that seeks to become an ONC–ATCB by requesting and subsequently submitting an application for ONC–ATCB status to the National Coordinator.

Deployment site means the physical location where a Complete EHR or EHR Module resides or is being or has been implemented.

Development site means the physical location where a Complete EHR or EHR Module was developed.

ONC–ATCB or ONC–Authorized Testing and Certification Body means an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to this subpart to perform the testing and certification of Complete EHRs and/or EHR Modules under the temporary certification program.

Remote testing and certification means the use of methods, including the use of web-based tools or secured electronic transmissions, that do not require an ONC–ATCB to be physically present at the development or deployment site to conduct testing and certification.

§ 170.405 Correspondence.

(a) Correspondence and communication with the National Coordinator shall be conducted by e-mail, unless otherwise necessary. The official date of receipt of any e-mail between the National Coordinator and an applicant for ONC–ATCB status or an ONC–ATCB is the day the e-mail was sent.

(b) In circumstances where it is necessary for an applicant for ONC–ATCB status or an ONC–ATCB to correspond or communicate with the National Coordinator by regular or express mail, the official date of receipt will be the date of the delivery confirmation.

§ 170.410 Types of testing and certification.

Applicants may seek authorization from the National Coordinator to perform the following types of testing and certification:

(a) Complete EHR testing and certification; and/or

(b) EHR Module testing and certification.

§ 170.415 Application prerequisite.

Applicants must request in writing an application for ONC–ATCB status from the National Coordinator. Applicants must indicate:

(a) The type of authorization sought pursuant to § 170.410; and

(b) If seeking authorization to perform EHR Module testing and certification, the specific type(s) of EHR Module(s) they seek authorization to test and certify. If qualified, applicants will only be granted authorization to test and certify the types of EHR Modules for which they seek authorization.

§ 170.420 Application.

The application for ONC–ATCB status consists of two parts. Applicants must complete both parts of the application in their entirety and submit them to the National Coordinator for the application to be considered complete.

(a) *Part 1.* An applicant must provide all of the following:

(1) General identifying information including:

(i) Name, address, city, state, zip code, and Web site of applicant; and

(ii) Designation of an authorized representative, including name, title, phone number, and e-mail address of the person who will serve as the applicant's point of contact.

(2) Documentation of the completion and results of a self-audit against all sections of ISO/IEC Guide 65:1996 (incorporated by reference in § 170.499), and the following:

(i) A description of the applicant's management structure according to section 4.2 of ISO/IEC Guide 65:1996;

(ii) A copy of the applicant's quality manual that has been developed according to section 4.5.3 of ISO/IEC Guide 65:1996;

(iii) A copy of the applicant's policies and approach to confidentiality according to section 4.10 of ISO/IEC Guide 65:1996;

(iv) A copy of the qualifications of each of the applicant's personnel who oversee or perform certification according to section 5.2 of ISO/IEC Guide 65:1996;

(v) A copy of the applicant's evaluation reporting procedures according to section 11 of ISO/IEC Guide 65:1996; and

(vi) A copy of the applicant's policies for use and display of certificates according to section 14 of ISO/IEC Guide 65:1996.

(3) Documentation of the completion and results of a self-audit against all sections of ISO/IEC 17025:2005 (incorporated by reference in § 170.499), and the following:

(i) A copy of the applicant's quality system document according to section 4.2.2 of ISO/IEC 17025:2005;

(ii) A copy of the applicant's policies and procedures for handling testing nonconformities according to section 4.9.1 of ISO/IEC 17025:2005; and

(iii) The qualifications of each of the applicant's personnel who oversee or conduct testing according to section 5.2 of ISO/IEC 17025:2005.

(4) An agreement, properly executed by the applicant's authorized representative, that it will adhere to the Principles of Proper Conduct for ONC–ATCBs.

(b) *Part 2.* An applicant must submit a completed proficiency examination.

§ 170.423 Principles of proper conduct for ONC–ATCBs.

An ONC–ATCB shall:

(a) Operate its certification program in accordance with ISO/IEC Guide 65:1996 (incorporated by reference in § 170.499) and testing program in accordance with

ISO/IEC 17025:2005 (incorporated by reference in § 170.499);

(b) Maintain an effective quality management system which addresses all requirements of ISO/IEC 17025:2005 (incorporated by reference in § 170.499);

(c) Attend all mandatory ONC training and program update sessions;

(d) Maintain a training program that includes documented procedures and training requirements to ensure its personnel are competent to test and certify Complete EHRs and/or EHR Modules;

(e) Use test tools and test procedures approved by the National Coordinator for the purposes of assessing Complete EHRs and/or EHR Modules compliance with the certification criteria adopted by the Secretary;

(f) Report to ONC within 15 days any changes that materially affect its:

(1) Legal, commercial, organizational, or ownership status;

(2) Organization and management, including key testing and certification personnel;

(3) Policies or procedures;

(4) Location;

(5) Facilities, working environment or other resources;

(6) ONC authorized representative (point of contact); or

(7) Other such matters that may otherwise materially affect its ability to test and certify Complete EHRs and/or EHR Modules;

(g) Allow ONC, or its authorized agents(s), to periodically observe on site (unannounced or scheduled) during normal business hours, any testing and/or certification performed to demonstrate compliance with the requirements of the temporary certification program;

(h) Provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been tested and certified which includes, at a minimum:

(1) The vendor name (if applicable);

(2) The date certified;

(3) The product version;

(4) The unique certification number or other specific product identification;

(5) The clinical quality measures to which a Complete EHR or EHR Module has been tested and certified;

(6) Where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary; and

(7) Where applicable, the certification criterion or criteria to which each EHR Module has been tested and certified.

(i) Retain all records related to tests and certifications according to ISO/IEC Guide 65:1996 (incorporated by reference in § 170.499) and ISO/IEC 17025:2005 (incorporated by reference in § 170.499) for the duration of the temporary certification program and provide copies of the final results of all completed tests and certifications to ONC at the conclusion of testing and certification activities under the temporary certification program;

(j) Promptly refund any and all fees received for:

(1) Requests for testing and certification that are withdrawn while its operations are suspended by the National Coordinator;

(2) Testing and certification that will not be completed as a result of its conduct; and

(3) Previous testing and certification that it performed if its conduct necessitates the recertification of Complete EHRs and/or EHR Modules;

(k) Ensure adherence to the following requirements when issuing a certification to Complete EHRs and/or EHR Modules:

(1) All certifications must require that a Complete EHR or EHR Module developer conspicuously include the following text on its Web site and in all marketing materials, communications statements, and other assertions related to the Complete EHR or EHR Module's certification:

(i) "This [Complete EHR or EHR Module] is 201[X]/201[X] compliant and has been certified by an ONC–ATCB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services or guarantee the receipt of incentive payments."; and

(ii) The information an ONC–ATCB is required to report to the National Coordinator under paragraph (h) of this section for the specific Complete EHR or EHR Module at issue;

(2) A certification issued to an integrated bundle of EHR Modules shall be treated the same as a certification issued to a Complete EHR for the purposes of paragraph (k)(1) of this section except that it must also indicate each EHR Module that comprises the bundle; and

(3) A certification issued to a Complete EHR or EHR Module based on applicable certification criteria adopted by the Secretary at subpart C of this part must be separate and distinct from any other certification(s) based on other criteria or requirements.

§ 170.425 Application submission.

(a) An applicant for ONC–ATCB status must submit its application either electronically via e-mail (or web submission if available), or by regular or express mail.

(b) An application for ONC–ATCB status may be submitted to the National Coordinator at any time during the existence of the temporary certification program.

§ 170.430 Review of application.

(a) *Method of review and review timeframe.*

(1) Applications will be reviewed in the order they are received.

(2) The National Coordinator will review Part 1 of the application in its entirety and determine whether Part 1 of the application is complete and satisfactory before proceeding to review Part 2 of the application in its entirety.

(3) The National Coordinator is permitted up to 30 days to review an application (submitted for the first time) upon receipt.

(b) *Application deficiencies.*

(1) If the National Coordinator identifies an area in an application that requires the applicant to clarify a statement or correct an error or omission, the National Coordinator may contact the applicant to make such clarification or correction without issuing a deficiency notice. If the National Coordinator has not received the requested information after five days, the applicant may be issued a deficiency notice specifying the error, omission, or deficient statement.

(2) If the National Coordinator determines that deficiencies in either part of the application exist, the National Coordinator will issue a deficiency notice to the applicant and return the application. The deficiency notice will identify the areas of the application that require additional information or correction.

(c) *Revised application.*

(1) An applicant is permitted to submit a revised application in response to a deficiency notice. An applicant may request an extension for good cause from the National Coordinator of the 15-day period provided in paragraph (c)(2) of this section to submit a revised application.

(2) In order to continue to be considered for ONC–ATCB status, an applicant's revised application must address the specified deficiencies and be received by the National Coordinator within 15 days of the applicant's receipt of the deficiency notice unless the National Coordinator grants an applicant's request for an extension of the 15-day period based on a finding of good cause. If a good cause extension is granted, then the revised application

must be received by the end of the extension period.

(3) The National Coordinator is permitted up to 15 days to review a revised application once it has been received and may request clarification of statements and the correction of errors or omissions in a revised application during this time period.

(4) If the National Coordinator determines that a revised application still contains deficiencies, the applicant will be issued a denial notice indicating that the applicant will no longer be considered for authorization under the temporary certification program. An applicant may request reconsideration of a denial in accordance with § 170.435.

(d) *Satisfactory application.*

(1) An application will be deemed satisfactory if it meets all application requirements, including a passing score on the proficiency examination.

(2) The National Coordinator will notify the applicant's authorized representative of its satisfactory application and its successful achievement of ONC–ATCB status.

(3) Once notified by the National Coordinator of its successful achievement of ONC–ATCB status, the applicant may represent itself as an ONC–ATCB and begin testing and certifying Complete EHRs and/or EHR Modules consistent with its authorization.

§ 170.435 ONC–ATCB application reconsideration.

(a) An applicant may request that the National Coordinator reconsider a denial notice issued for each part of an application only if the applicant can demonstrate that clear, factual errors were made in the review of the applicable part of the application and that the errors' correction could lead to the applicant obtaining ONC–ATCB status.

(b) *Submission requirement.* An applicant is required to submit, within 15 days of receipt of a denial notice, a written statement to the National Coordinator contesting the decision to deny its application and explaining with sufficient documentation what factual errors it believes can account for the denial. If the National Coordinator does not receive the applicant's submission within the specified timeframe, its reconsideration request may be rejected.

(c) *Reconsideration request review.* If the National Coordinator receives a timely reconsideration request, the National Coordinator is permitted up to 15 days from the date of receipt to review the information submitted by the applicant and issue a decision.

(d) *Decision.*

(1) If the National Coordinator determines that clear, factual errors were made during the review of the application and that correction of the errors would remove all identified deficiencies, the applicant's authorized representative will be notified of the National Coordinator's decision to reverse the previous decision(s) not to approve part of the applicant's application or the entire application.

(i) If the National Coordinator's decision to reverse the previous decision(s) affected part 1 of an application, the National Coordinator will subsequently review part 2 of the application.

(ii) If the National Coordinator's decision to reverse the previous decision(s) affected part 2 of an application, the applicant's authorized representative will be notified of the National Coordinator's decision as well as the applicant's successful achievement of ONC–ATCB status.

(2) If, after reviewing an applicant's reconsideration request, the National Coordinator determines that the applicant did not identify any factual errors or that correction of those factual errors would not remove all identified deficiencies in the application, the National Coordinator may reject the applicant's reconsideration request.

(3) *Final decision.* A reconsideration decision issued by the National Coordinator is final and not subject to further review.

§ 170.440 ONC–ATCB status.

(a) *Acknowledgement and publication.* The National Coordinator will acknowledge and make publicly available the names of ONC–ATCBs, including the date each was authorized and the type(s) of testing and certification each has been authorized to perform.

(b) *Representation.* Each ONC–ATCB must prominently and unambiguously identify the scope of its authorization on its Web site, and in all marketing and communications statements (written and oral) pertaining to its activities under the temporary certification program.

(c) *Renewal.* ONC–ATCB status does not need to be renewed during the temporary certification program.

(d) *Expiration.* The status of all ONC–ATCBs will expire upon the sunset of the temporary certification program in accordance with § 170.490.

§ 170.445 Complete EHR testing and certification.

(a) An ONC–ATCB must test and certify Complete EHRs to all applicable certification criteria adopted by the Secretary at subpart C of this part.

(b) An ONC–ATCB must provide the option for a Complete EHR to be tested and certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) *Inherited certified status.* An ONC–ATCB must accept requests for a newer version of a previously certified Complete EHR to inherit the previously certified Complete EHR's certified status without requiring the newer version to be retested and recertified.

(1) Before granting certified status to a newer version of a previously certified Complete EHR, an ONC–ATCB must review an attestation submitted by the developer of the Complete EHR to determine whether the newer version has adversely affected any previously certified capabilities.

(2) An ONC–ATCB may grant certified status to a newer version of a previously certified Complete EHR if it determines that previously certified capabilities have not been adversely affected.

(d) An ONC–ATCB that has been authorized to test and certify Complete EHRs is also authorized to test and certify all EHR Modules under the temporary certification program.

§ 170.450 EHR module testing and certification.

(a) When testing and certifying EHR Modules, an ONC–ATCB must test and certify in accordance with the applicable certification criterion or certification criteria adopted by the Secretary at subpart C of this part.

(b) An ONC–ATCB must provide the option for an EHR Module or a bundle of EHR Modules to be tested and certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) *Privacy and security testing and certification.* EHR Modules shall be tested and certified to all privacy and security certification criteria adopted by the Secretary unless the EHR Module(s) is/are presented for testing and certification in one of the following manners:

(1) The EHR Module(s) is/are presented for testing and certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR (as defined in 45 CFR 170.102), and one or more of the constituent EHR Modules is/are demonstrably responsible for providing all of the privacy and security

capabilities for the entire bundle of EHR Module(s); or

(2) An EHR Module is presented for testing and certification, and the presenter can demonstrate and provide documentation to the ONC–ATCB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be tested and certified in accordance with such certification criterion.

(d) *Inherited certified status.* An ONC–ATCB must accept requests for a newer version of a previously certified EHR Module or bundle of EHR Modules to inherit the previously certified EHR Module's or bundle of EHR Modules certified status without requiring the newer version to be retested and recertified.

(1) Before granting certified status to a newer version of a previously certified EHR Module or bundle of EHR Modules, an ONC–ATCB must review an attestation submitted by the developer of the EHR Module or presenter of the bundle of EHR Modules to determine whether the newer version has adversely affected any previously certified capabilities.

(2) An ONC–ATCB may grant certified status to a newer version of a previously certified EHR Module or bundle of EHR Modules if it determines that previously certified capabilities have not been adversely affected.

§ 170.455 Testing and certification to newer versions of certain standards.

(a) ONC–ATCBs may test and certify Complete EHRs and EHR Module to a newer version of certain identified minimum standards specified at subpart B of this part if the Secretary has accepted a newer version of an adopted minimum standard.

(b) Applicability of an accepted new version of an adopted minimum standard.

(1) ONC–ATCBs are not required to test and certify Complete EHRs and/or EHR Modules according to newer versions of an adopted minimum standard accepted by the Secretary until the incorporation by reference provision of the adopted version is updated in the **Federal Register** with a newer version.

(2) Certified EHR Technology may be upgraded to comply with newer versions of an adopted minimum standard accepted by the Secretary without adversely affecting the certification status of the Certified EHR Technology.

§ 170.457 Authorized testing and certification methods.

An ONC–ATCB must provide remote testing and certification for both development and deployment sites.

§ 170.460 Good standing as an ONC–ATCB.

An ONC–ATCB must maintain good standing by:

(a) Adhering to the Principles of Proper Conduct for ONC–ATCBs;

(b) Refraining from engaging in other types of inappropriate behavior, including an ONC–ATCB misrepresenting the scope of its authorization as well as an ONC–ATCB testing and certifying Complete EHRs and/or EHR Modules for which it does not have authorization; and

(c) Following all other applicable Federal and state laws.

§ 170.465 Revocation of authorized testing and certification body status.

(a) *Type-1 violations.* The National Coordinator may revoke an ONC–ATCB's status for committing a Type-1 violation. Type-1 violations include violations of law or temporary certification program policies that threaten or significantly undermine the integrity of the temporary certification program. These violations include, but are not limited to: False, fraudulent, or abusive activities that affect the temporary certification program, a program administered by HHS or any program administered by the Federal government.

(b) *Type-2 violations.* The National Coordinator may revoke an ONC–ATCB's status for failing to timely or adequately correct a Type-2 violation. Type-2 violations constitute noncompliance with § 170.460.

(1) *Noncompliance notification.* If the National Coordinator obtains reliable evidence that an ONC–ATCB may no longer be in compliance with § 170.460, the National Coordinator will issue a noncompliance notification with reasons for the notification to the ONC–ATCB requesting that the ONC–ATCB respond to the alleged violation and correct the violation, if applicable.

(2) *Opportunity to become compliant.* After receipt of a noncompliance notification, an ONC–ATCB is permitted up to 30 days to submit a written response and accompanying documentation that demonstrates that no violation occurred or that the alleged violation has been corrected.

(i) If the ONC–ATCB submits a response, the National Coordinator is permitted up to 30 days from the time the response is received to evaluate the response and reach a decision. The National Coordinator may, if necessary, request additional information from the ONC–ATCB during this time period.

(ii) If the National Coordinator determines that no violation occurred or that the violation has been sufficiently corrected, the National Coordinator will issue a memo to the ONC–ATCB confirming this determination.

(iii) If the National Coordinator determines that the ONC–ATCB failed to demonstrate that no violation occurred or to correct the area(s) of non-compliance identified under paragraph (b)(1) of this section within 30 days of receipt of the noncompliance notification, then the National Coordinator may propose to revoke the ONC–ATCB's status.

(c) *Proposed revocation.*

(1) The National Coordinator may propose to revoke an ONC–ATCB's status if the National Coordinator has reliable evidence that the ONC–ATCB committed a Type-1 violation; or

(2) The National Coordinator may propose to revoke an ONC–ATCB's status if, after the ONC–ATCB has been notified of a Type-2 violation, the ONC–ATCB fails to:

(i) To rebut the finding of a violation with sufficient evidence showing that the violation did not occur or that the violation has been corrected; or

(ii) Submit to the National Coordinator a written response to the noncompliance notification within the specified timeframe under paragraph (b)(2).

(d) *Suspension of an ONC–ATCB's operations.*

(1) The National Coordinator may suspend the operations of an ONC–ATCB under the temporary certification program based on reliable evidence indicating that:

(i) The ONC–ATCB committed a Type-1 or Type-2 violation; and

(ii) The continued testing and certification of Complete EHRs and/or EHR Modules by the ONC–ATCB could have an adverse impact on the health or safety of patients.

(2) If the National Coordinator determines that the conditions of paragraph (d)(1) have been met, an ONC–ATCB will be issued a notice of proposed suspension.

(3) Upon receipt of a notice of proposed suspension, an ONC–ATCB will be permitted up to 3 days to submit a written response to the National Coordinator explaining why its operations should not be suspended.

(4) The National Coordinator is permitted up to 5 days from receipt of an ONC–ATCB's written response to a notice of proposed suspension to review the response and make a determination.

(5) The National Coordinator may make one of the following determinations in response to the ONC–ATCB's written response or if the ONC–ATCB fails to submit a written response within the timeframe specified in paragraph (d)(3):

(i) Rescind the proposed suspension; or

(ii) Suspend the ONC–ATCB's operations until it has adequately corrected a Type-2 violation; or

(iii) Propose revocation in accordance with § 170.465(c) and suspend the ONC–ATCB's operations for the duration of the revocation process.

(6) A suspension will become effective upon an ONC–ATCB's receipt of a notice of suspension.

(e) *Opportunity to respond to a proposed revocation notice.*

(1) An ONC–ATCB may respond to a proposed revocation notice, but must do so within 10 days of receiving the proposed revocation notice and include appropriate documentation explaining in writing why its status should not be revoked.

(2) Upon receipt of an ONC–ATCB's response to a proposed revocation notice, the National Coordinator is permitted up to 30 days to review the information submitted by the ONC–ATCB and reach a decision.

(3) Unless suspended, an ONC–ATCB will be permitted to continue its operations under the temporary certification program during the time period provided for the ONC–ATCB to respond to the proposed revocation notice and the National Coordinator to review the response.

(f) *Good standing determination.* If the National Coordinator determines that an ONC–ATCB's status should not be revoked, the National Coordinator will notify the ONC–ATCB's authorized representative in writing of this determination.

(g) *Revocation.*

(1) The National Coordinator may revoke an ONC–ATCB's status if:

(i) A determination is made that revocation is appropriate after considering the information provided by the ONC–ATCB in response to the proposed revocation notice; or

(ii) The ONC–ATCB does not respond to a proposed revocation notice within the specified timeframe in paragraph (d)(1) of this section.

(2) A decision to revoke an ONC–ATCB's status is final and not subject to further review unless the National Coordinator chooses to reconsider the revocation.

(h) *Extent and duration of revocation.*

(1) The revocation of an ONC–ATCB is effective as soon as the ONC–ATCB receives the revocation notice.

(2) A testing and certification body that has had its ONC–ATCB status revoked is prohibited from accepting new requests for testing and certification and must cease its current testing and certification operations under the temporary certification program.

(3) A testing and certification body that has had its ONC–ATCB status revoked for a Type-1 violation is prohibited from reapplying for ONC–ATCB status under the temporary certification program for one year. If the temporary certification program sunsets during this time, the testing and certification body is prohibited from applying for ONC–ACB status under the permanent certification program for the time that remains within the one year prohibition.

(4) The failure of a testing and certification body that has had its ONC–ATCB status revoked, to promptly refund any and all fees for tests and/or certifications of Complete EHRs and EHR Modules not completed will be considered a violation of the Principles of Proper Conduct for ONC–ATCBs and will be taken into account by the National Coordinator if the testing and certification body reapplies for ONC–ATCB status under the temporary certification program or applies for ONC–ACB status under the permanent certification program.

§ 170.470 Effect of revocation on the certifications issued to complete EHRs and EHR Modules.

(a) The certified status of Complete EHRs and/or EHR Modules certified by an ONC–ATCB that had it status revoked will remain intact unless a Type-1 violation was committed that calls into question the legitimacy of the certifications issued by the former ONC–ATCB.

(b) If the National Coordinator determines that a Type-1 violation occurred that called into question the legitimacy of certifications conducted by the former ONC–ATCB, then the National Coordinator would:

(1) Review the facts surrounding the revocation of the ONC–ATCB's status; and

(2) Publish a notice on ONC's Web site if the National Coordinator believes that Complete EHRs and/or EHR Modules were improperly certified by the former ONC–ATCB.

(c) If the National Coordinator determines that Complete EHRs and/or EHR Modules were improperly certified, the certification status of affected Complete EHRs and/or EHR Modules would only remain intact for 120 days after the National Coordinator publishes the notice. The certification status of the Complete EHR and/or EHR Module can only be maintained thereafter by being re-certified by an ONC–ATCB in good standing.

§ 170.490 Sunset of the temporary certification program.

(a) The temporary certification program will sunset on December 31, 2011, or if the permanent certification program is not fully constituted at that time, then upon a subsequent date that is determined to be appropriate by the National Coordinator. On and after the temporary certification program sunset date, ONC–ATCBs will be prohibited from accepting new requests to test and certify Complete EHRs or EHR Modules.

(b) ONC–ATCBs are permitted up to six months after the sunset date to complete all testing and certification activities associated with requests for testing and certification of Complete EHRs and/or EHR Modules received prior to the sunset date.

§ 170.499 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Also, it is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave, SW., Washington, DC 20201, call ahead to arrange for inspection at 202–690–7151, and is available from the source listed below.

(b) International Organization for Standardization, Case postale 56, CH·1211, Geneve 20, Switzerland, telephone +41–22–749–01–11, *http://www.iso.org.*

(1) ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories (Second Edition), May 15, 2005, IBR approved for § 170.420 and § 170.423.

(2) ISO/IEC GUIDE 65 General Requirements for Bodies Operating Product Certification Systems (First

Edition), 1996, IBR approved for § 170.420 and § 170.423.

(3) [Reserved]

Dated: June 8, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–14999 Filed 6–18–10; 11:15 am]

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Thursday,
June 24, 2010

Part III

Nuclear Regulatory Commission

10 CFR Parts 30, 31, 32, et al.
Requirements for Distribution of Byproduct Material; Proposed Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 31, 32, 40, and 70

RIN 3150–AH91

[NRC–2008–0338]

Requirements for Distribution of Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to make requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up to date. The Commission is also proposing to redefine categories of devices to be used under exemptions, add explicit provisions regarding the sealed source and device registration process, and add flexibility to the licensing of users of sealed sources and devices. This action is primarily intended to make licensing processes more efficient and effective. These changes would affect manufacturers and distributors of sources and devices containing byproduct material and future users of some products currently used under a general or specific license.

DATES: The comment period expires September 7, 2010. Submit comments specific to the information collections aspects of this rule by July 26, 2010. Comments received after these dates will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before these dates.

ADDRESSES: Please include Docket ID NRC–2008–0338 in the subject line of your comments. For instructions on submitting comments and accessing documents related to this action, see Section I, "Submitting Comments and Accessing Information" in the **SUPPLEMENTARY INFORMATION** section of this document. You may submit comments by any one of the following methods.

Federal Rulemaking Web Site: Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2008–0338 Address questions about NRC dockets to Carol Gallagher, telephone 301–492–3668; e-mail *Carol.Gallagher@nrc.gov.*

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: Rulemaking.Comments@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301–415–1966.

Hand Deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852 between 7:30 a.m. and 4:15 p.m. during Federal workdays (Telephone 301–415–1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.

You may submit comments on the information collections by the methods indicated in the Paperwork Reduction Act Statement.

FOR FURTHER INFORMATION CONTACT: Catherine R. Mattsen, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone 301–415–6264, e-mail, *Catherine.Mattsen@nrc.gov.*

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I. Submitting Comments and Accessing Information

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site *http://www.regulations.gov.* Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

You can access publicly available documents related to this document using the following methods:

NRC's Public Document Room (PDR): The public may examine and have copied for a fee, publicly available documents at the NRC's PDR, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

NRC's Agencywide Documents Access and Management System (ADAMS): Publicly available documents created or received at the NRC are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, or 301–415–4737, or by e-mail to *PDR.Resource@nrc.gov.*

Federal Rulemaking Web site: Public comments and supporting materials related to this proposed rule can be found at *http://www.regulations.gov* by searching on Docket ID NRC–2008–0338.

II. Background

A. Introduction

The Commission has authority to issue both general and specific licenses for the use of byproduct material and also to exempt byproduct material from regulatory control under section 81 of the Atomic Energy Act of 1954, as amended (hereafter, "the Act" or the AEA). A general license is provided by regulation, grants authority to a person for particular activities involving byproduct material as described within the general license, and is effective without the filing of an application with the Commission or the issuance of a licensing document to a particular person. Requirements for general licensees appear in the regulations and are designed to be commensurate with the specific circumstances covered by each general license. A specific license is issued to a named person who has filed an application with the Commission.

In considering its exemptions from licensing, the Commission is directed by the Act to make "a finding that the exemption of such classes or quantities of such material or such kinds of uses or users will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public." As beneficial uses of radioactive material were developed and experience grew, new products intended for use by the general public were invented and the regulations were amended to accommodate the use of new products.

Although presenting very low risks of significant individual doses to members of the general public, exempt products are a source of routine exposure to the public. A substantial portion of the population uses and enjoys benefits from exempt products, such as smoke detectors, but also receives some radiation exposure from those products. In keeping with its consumer product policy, which calls for the Commission to evaluate the total effect of consumer products on the public, the Commission conducted a systematic reevaluation of the exemptions from licensing. A major part of the effort was an assessment of the potential and likely doses to workers and the public under these exemptions. Dose assessments for most of these exemptions can be found in NUREG–1717 [1], "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," June 2001. Actual exposures of the public likely to occur are in line with Commission policy concerning acceptable doses from products and materials used under exemptions. For some exemptions, there was a significant difference between potential and likely doses because the use of the exemption is limited or nonexistent, or significantly lower quantities are used in products than is potentially allowed under the exemption.

The NRC has reviewed the regulations governing the distribution of byproduct material to persons for use under the exemptions, as well as other regulations governing distribution of products containing byproduct material. The Commission decided to make these regulations more flexible, user-friendly, and performance-based, and to improve its ability to risk-inform its regulatory program. These concepts have been considered in developing potential revisions to the regulatory program in the area of distribution of byproduct material.

In a final rule published October 16, 2007 (72 FR 58473), some of these revisions were made, including the removal of obsolete exemptions. This action is a follow-on to that effort. To make optimal use of rulemaking resources, both for the NRC and the States who must develop conforming regulations, several issues have been combined into this proposed rule.

B. Regulatory Framework

The Commission's regulations in Part 30 contain the basic requirements for licensing of byproduct material. Part 30 includes a number of provisions that exempt the end user from licensing requirements, so-called "exemptions." Some exemptions are product-specific, intended only for specific purposes which are narrowly defined by regulation. More broadly defined are the general materials exemptions, which allow the use of many radionuclides in many chemical and physical forms subject to limits on activity, and which are specified in §§ 30.14 and 30.18 for exempt concentrations and exempt quantities, respectively. The Commission's regulations also include two class exemptions—for self-luminous products and gas and aerosol detectors, in §§ 30.19 and 30.20, respectively—which cover a broad class of products not limited to certain quantities or radionuclides. Under the class exemptions, many products can be approved for use through the licensing process if the applicant demonstrates that the specific product is within the class and meets certain radiation dose criteria.

Part 31 provides general licenses for the use of certain items containing byproduct material and the requirements associated with these general licenses. The general licenses are established in §§ 31.3, 31.5, 31.7, 31.8, 31.10, 31.11, and 31.12.

Part 32 sets out requirements for the manufacture or initial transfer (distribution) of items containing byproduct material to persons exempt from licensing requirements and to persons using a general license. It also includes requirements applicable to certain manufacturers and distributors of products and materials to be used by specific licensees. The requirements for distributors address such measures as prototype testing, labeling, reporting and recordkeeping, quality control, and, in some cases, specific sampling procedures.

III. Proposed Actions

This proposed rule would make a number of revisions to the regulations governing the use of byproduct material under exemptions from licensing and under general license, and to the requirements for those who distribute products and materials. The changes are intended to improve the efficiency and effectiveness of certain licensing actions.

A. Actions Related to Sealed Source and Device Registration

A.1 Updating Regulations To Add Registration Requirements

Section 32.210 provides for the registration of sealed sources and devices containing sealed sources intended for use under a specific license. Manufacturers or distributors may submit a request to NRC for an evaluation of radiation safety information for a product and for registration of the product. After satisfactory completion of the evaluation, the NRC issues a certificate of registration to the person making the request. Subsequently, under § 30.32(g), specific licensees or applicants for a specific license who wish to use the registered product need only identify the source or device by manufacturer and model number as registered with the Commission under § 32.210 or with an Agreement State in their applications. Because the source or device has already been evaluated and its safety information is a matter of record, the users are not required to submit the detailed radiation safety information for the source or device in their license applications. This greatly simplifies the licensing process for the users of specifically licensed sources and devices. The registration system is referred to as the Sealed Source and Device (SS & D) Registry. Many Agreement States have similar registration procedures. Registration certificates for the sources and devices reviewed by the Agreement States are also added to the national SS & D Registry. However, some Agreement

[1] NUREG–1717 is a historical document developed using the models and methodology available in the 1990s. The NUREG provides the estimate of the radiological impacts of the various exemptions from licensing based on what was known about distribution of material under the exemptions in the early 1990s. NUREG–1717 was used as the initial basis for evaluating the regulations for exemptions from licensing requirements and determining whether those regulations adequately ensured that the health and safety of the public were protected consistent with NRC policies related to radiation protection. The agency will not use the results presented in NUREG–1717 as a sole basis for any regulatory decisions or future rulemaking without additional analysis. Copies of NUREGs may be purchased from the Superintendent of Documents, U. S. Government Printing Office, P.O. Box 37082, Washington, DC 20013–7082. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is also available for inspection and/or copying for a fee at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Public File Area O1–F21, Rockville, MD.

States do not include the evaluation and registration of sealed sources and devices in their agreements; authority for these reviews remains under NRC regulatory jurisdiction.

A definition of the registry is included in § 35.2 as follows: "*Sealed Source and Device Registry* means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product." This same definition would be added to 10 CFR part 32 by this action, as the information requirements for the SS & D review and registration are in part 32. The SS & D Registry is maintained in a computer database, which is available to the Agreement States. While this process, in which the manufacturer or initial distributor obtains a registration certificate for the source or device, is generally used for most specifically licensed sources and devices, in some cases of custom-made sources or devices, the planned user will sometimes submit the detailed radiation safety information. As a matter of licensing practice, such a custom device, if containing more than certain quantities of radioactive material, is also registered; however, it only allows for the use of the custom-made source or device by the specified user. As § 30.32(g) requires the radiation safety information to be submitted by applicants to use sealed sources and devices if they are not registered, manufacturers and distributors generally register the sources and devices that are to be used under a specific license. Sealed source or device review and registration are conducted for most sealed sources and devices to be used under a specific license.

This registration process has also been extended to many generally licensed and some exempt products. The regulations in 10 CFR part 32 contain requirements for submittal of radiation safety information concerning these products by the manufacturer or initial distributor. Although registration of these products by the manufacturer or initial distributor is not addressed by the regulations, the NRC's licensing practice is to issue registration certificates for certain of these products based on the radiation safety information submitted. Also, fees are assessed based on whether or not a "sealed source and/or device review" is required.

The products in each of these categories for which the registration process is used as part of the licensing process are indicated in guidance, e.g., NUREG–1556, Vol. 3, Rev. 1, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration"; NUREG–1556, Vol. 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses"; and NUREG–1556, Vol. 16, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licenses." For a number of categories of specifically licensed sources and devices, an explicit requirement for registration is included in the regulations. Existing specific requirements include §§ 35.400, 35.500, 35.600, 36.21, and 39.41(f). These concern certain medical use products, sealed sources installed in irradiators after July 1, 1993, and energy compensation sources (a specific type of reference source used in well logging).

The only products used under exemption from licensing for which the NRC issues registration certificates are those distributed for use under a "class exemption." As noted earlier, a class exemption allows for the use under exemption of a category of products with the safety decision for individual products made through the licensing process. The safety review for these products includes evaluating the product against specific safety criteria contained in the regulations in 10 CFR part 32. The regulations currently contain two class exemptions. These are found in § 30.19, Self-luminous products containing tritium, krypton-85, or promethium-147, and § 30.20, Gas and aerosol detectors containing byproduct material, and equivalent Agreement State regulations. As discussed later in this document, this proposed rule would establish a third class exemption for certain industrial products.

In the case of generally licensed products, sealed source and device registration certificates are issued for products distributed for use under §§ 31.3, 31.5, 31.7, and 31.10, and equivalent Agreement State regulations. (Note that this registration is distinct and different in scope and purpose from the registration of devices by some general licensees under § 31.5(c)(13).)

Neither general licensees nor persons exempt from licensing requirements need to submit any safety information in order to obtain a product. For these products, however, the registration process also serves the important purpose of providing information to the regulators in all jurisdictions. Products are approved by NRC and, in some cases, by the various Agreement States for distribution to all jurisdictions. For those products that are registered by the manufacturer or distributor, the registration information is available to NRC and all of the Agreement States through the SS & D Registry. In this way, the various jurisdictions can be assured of the radiation safety of the products being used under their regulations that have been evaluated by another jurisdiction. The registration of products by model number also assists in the tracking of generally licensed devices by NRC and the Agreement States. In some cases, a secondary distributor of a generally licensed device may refer to the registration certificate obtained by the manufacturer, or more frequently a source to be installed in a generally licensed device may be manufactured by a different entity who has registered the source separately.

For those products used under a product-specific exemption, for which registration certificates are not issued, the safety of the product has been evaluated based primarily on the constraints contained in the regulations, such as a quantity limit for a specific radionuclide, and what can be projected about the life cycle of the product and how it is used. Some of these evaluations are documented in NUREG/CR–1775, "Environmental Assessment of Consumer Products Containing Radioactive Material," October 1980 (available at the NRC's electronic Reading Room, ADAMS Accession No. ML082910862), and NUREG–1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," June 2001. The applicable requirements in § 32.14(b) require information to be submitted to allow an evaluation of the potential radiation exposure and in accordance with § 32.14(d), the NRC makes a determination that the byproduct material is "properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling." But the information to support this evaluation of the particular product is not considered necessary to routinely provide to the Agreement States through the SS & D Registry.

No sealed source and device review is conducted for the products used under the general licenses in § 31.8 or § 31.11. The general license in § 31.8 is specifically for no more than 0.185 MBq (5 μCi) of americium-241 or radium-226 in the form of calibration and reference sources, and applies only to specific licensees. The safety of these sources is also well established, with the

individual product being reviewed and approved in the licensing process. The general license in § 31.11 pertains to in-vitro clinical or laboratory testing using prepackaged units containing certain limited quantities of byproduct material, e.g., iodine-125 in units not exceeding 10 μCi (0.37 MBq). These in vitro kits are not sealed sources or devices. They can be used only by physicians, clinical laboratories, hospitals, and practitioners of veterinary medicine who preregister with the Commission and by part 35 licensees. There is also no SS & D registration for the recently added general license in § 31.12, which covers only items produced prior to the NRC gaining jurisdiction over radium-226. Because there is no allowance for future production of items to be used under this general license, there are no associated distributor requirements and thus, no requirement for a product to be registered in the SS & D Registry. These products are mostly antiquities produced before States had regulations similar to NRC's.

Registration certificates are issued for most specifically licensed sealed sources and devices. The exceptions are for small calibration and reference sources and for sources and devices to be used by (1) Broad scope licensees under part 33 and equivalent Agreement State regulations, (2) research and development licensees, and (3) licensees for whom the source or device was built to their unique specifications and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide. These three categories of licensees must be qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form as indicated in their license(s). Under these circumstances, licensing these three types of users does not rely on the inherent safety features of the source or device; users will be evaluated under the criteria in § 30.33(a)(2) and (3) and licensed to handle equivalent quantities of the materials in any form. If the source is registered but not the device, the users must be licensed to handle equivalent quantities of the materials in unshielded form.

For specifically licensed calibration and reference sources, the proposed quantity cutoffs for small sources excluded from the requirement for registration are 0.37 MBq (10 μCi) for alpha emitters and 37 MBq (1 mCi) for beta and/or gamma emitters. This is a simplification from current licensing practice, which uses a limit of 3.7 MBq (100 μCi) or ten times the quantity specified in § 30.71, whichever is greater, for beta and/or gamma emitters. The limits using current guidance for beta/gamma emitters range from 3.7 MBq (100 μCi) to 370 MBq (10 mCi). Thus, for any particular radionuclide, the proposed criterion is no more than ten times higher to ten times lower than current practice. As certificates typically cover a large number of radionuclides for this type of sealed source, this change from current practice is not expected to affect the overall number of registration certificates issued.

The proposed rule would explicitly add registration requirements to the regulations for byproduct material in products used under general licenses and under exemptions from licensing requirements, as well as for additional specifically licensed sources and devices for which this is not currently addressed by the regulations. This will make it easier for potential applicants for a license to distribute these products to determine the applicable requirements and associated fees. These proposed provisions are in large part consistent with present licensing practice. They would appear in §§ 32.22(a)(3)(ii), 32.26(c)(2), 32.30(c)(3), 32.51(a)(6), 32.53(f), 32.61(g), 32.74(a)(4), and 32.210.

A.2 Adding Provisions for Amendment, Modification and Revocation, Review, and Inactivation of Registration Certificates

The Commission is adding a number of other explicit provisions to the regulations concerning registration certificates. Many certificates are revised and updated from time to time as a result of amendment requests made by manufacturers or distributors to accommodate desired changes in a product or associated procedures or to add new products to a registration certificate covering a series of models. Sections 30.38 and 30.39, which currently address only amendment of licenses, would be revised to also address amendment of registration certificates.

Unlike specific licenses, registration certificates are not issued with expiration dates. If a significant safety issue arises with a product, regulatory means are available to address it, such as an order issued to a distributor to cease distribution until the safety issue is resolved. The Commission has authority to request additional information or to modify requirements under the general provisions in §§ 2.204, 30.34(e), and 30.61. In addition, since the Commission has authority to revoke a license, and registration is used as part of the licensing process, the Commission has the authority to revoke a registration certificate, if for example, it determines that the registration is inconsistent with current regulatory standards. However, the current regulations do not reference this authority. Therefore, § 30.61 is being revised to explicitly implement the Commission's authority to modify or revoke registration certificates.

As a registration certificate, in conjunction with the license, authorizes distribution of a product, a certificate may be reevaluated at the time of license renewal. Generally, this has not been the practice of NRC, but may be the case for some Agreement States. In the case of licenses authorizing distribution to exempt persons, a limited review of the certificate(s), when applicable, has typically been conducted to ensure that the information is complete and accurate with respect to any changes that may have occurred since issuance of the certificate. For all types of certificates, it is important that there be consistency between the license and the certificate(s).

The Commission does not believe that it is necessary to conduct a complete reevaluation of sealed sources and devices at the time that distribution licenses are renewed, usually every 10 years, since generally, there are fewer safety significant aspects that are likely to change reflected in the registration certificate than those addressed in the license. The Commission does recognize a need to update registration certificates and currently relies, for the most part, on certificate holders to request amendments of certificates, as appropriate. One factor is that the NRC is required to consider the application of industry standards, for example, as reflected in § 32.210(d). These industry standards may be updated to provide improved safety. Also, licensees are required by § 20.1101 to implement radiation protection programs and to use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA). Thus, it is appropriate for licensees to consider new developments in technology and standards as they may impact ALARA in the design of products. However, because § 32.210(f) requires the certificate holder to manufacture and distribute products in accordance with the provisions of the registration certificate and any statements made in the request for registration, and no reevaluation of a source or device, once approved, is normally required, the current

regulatory structure may limit rather than encourage industry improvement.

There may be reasons to reevaluate a sealed source or device in some circumstances with regard to either the actual design of a source or device, or such other aspects as quality assurance or information provided to the user on safe use. While the current regulations provide adequate authority to do so, recalling a registration certificate for review and reissuance in the absence of a significant safety problem with the product is an activity very rarely conducted by NRC in the past. This proposed rule also includes an explicit provision to specifically address such a process in § 32.210(h). The Commission would complete its evaluation in accordance with the criteria specified in § 32.210. As noted under Section III. A.1, "Updating Regulations to Add Registration Requirements," of this document, this proposed rule would add specific provisions delineating which sealed sources and devices must be registered in the SS & D, broadening the applicability of § 32.210 to some generally licensed and exempt products. The Commission may use the proposed provision in § 32.210(h) to update the certificate with respect to applicable industry standards or current security concerns or to ensure the quality of the summary of safety information and the information on conditions of use contained in the registration certificate that is available to the various jurisdictions. The Commission specifically seeks comment on the circumstances under which such a reevaluation should be made and also on how such a reevaluation may be conducted with minimum impact to industry.

The Commission requests comment on how it might best provide for the update of registration certificates so as not to discourage improvement in the design of sources or devices, more readily allow for the application of updated industry standards, and ensure that information in the certificates is fully consistent with current practices. In addition to the proposed provision in § 32.210(h), other options could include reviewing certificates at the time of license renewal, in part or in whole; adding separate expiration dates to certificates with typically longer terms than licenses, e.g., 10 to 20 years; and explicitly allowing licensees to make changes without NRC approval, if these changes do not reduce safety margins.

Generally, the Commission has not previously made standards more restrictive with regard to products to be used under a general license or under an exemption from licensing, such as to restrict further distribution of a previously approved product. However, in a separate action, the Commission has proposed to revise § 31.5 to restrict quantities of certain radionuclides that are authorized under the general license (August 3, 2009; 74 FR 38372). That action would impact the authority to distribute certain devices. The Commission therefore seeks comment on how certificates for devices previously approved for use under the general license in § 31.5 (and equivalent Agreement State provisions) should be reevaluated and required to meet such new limits. In addition, the Commission seeks comments on how the NRC might use the proposed provision for review in § 32.210(h) in relation to any changes in standards for products or applicable limits with respect to continued distribution, such as under what circumstances distribution of a product should be stopped by a certain date, or under what circumstances changes to individual certificates might be considered on a case-by-case basis.

Currently, registrations in the SS & D Registry are kept active until a distributor who is no longer distributing a particular source or device, requests to change the status. At this point, the registration is changed to inactive status, meaning that the covered products are no longer authorized to be distributed. Annual fees are assessed by NRC only for active registrations. The SS & D registrations are kept indefinitely in inactive status after authorization to distribute has ceased, so that the registration information is available for sources and devices previously distributed and possibly still in use.

Because some States do not have annual fees for maintaining active SS & D certificates, distributors do not consistently request inactivation of certificates, leaving active certificates in the database that do not reflect any continued distribution. This somewhat limits the information available to other jurisdictions as to what sources and devices are authorized for continued distribution. This rule includes a proposed provision for inactivation (§ 32.211), which would require distributors to request inactivation of certificates within 2 years following the last initial transfer of a source or device covered by the certificate. Two years was chosen to minimize any impact on certificate holders. NRC certificate holders typically request inactivation of certificates within about a year. This provision is expected to improve the consistency of this approach across jurisdictions through the addition of equivalent provisions to Agreement State regulations, and thus, the quality of the information concerning current distribution available to regulators.

A.3 Adding Flexibility for Licensing Users of Sealed Sources and Devices

As noted, the safety information for every sealed source and device to be used under a specific license is not included in the SS & D Registry. However, the wording of § 30.32(g) has not allowed as much flexibility as was expected when this provision was added to the regulations. In some circumstances, it has been impractical or impossible for users to provide all of the information required by § 30.32(g). This has caused some applicants and licensees renewing their licenses to seek exemptions from § 30.32(g) for the use of products for which the manufacturer or distributor has not obtained an SS & D registration.

In addition to providing criteria in a proposed revision to § 32.210 for situations where an SS & D registration would not be required, revisions to § 30.32(g) are also being proposed which would accommodate exceptions made in the SS & D registration process. In particular, a proposed § 30.32(g)(4) would provide that limited information would be required for the smaller calibration and reference sources that are not registered. Also included is a proposed provision to allow for licenses to be issued without the need for every individual sealed source or device to be used to be identified by the applicant. A proposed § 30.32(g)(5) would allow an applicant to propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used as an alternative to identifying each sealed source and device individually.

This latter provision is not intended as a broadly applied change in the approach to licensing the use of sealed sources and devices. This change is intended to accommodate certain expected situations in which having to identify each sealed source or device presents an undue burden. For example, military applicants are sometimes unable to identify exactly which product they may be procuring. This provision could also be used by the types of applicants/licensees identified in proposed § 32.210(g)(2), namely those licensed for research and development (R & D), those licensed under part 33, and certain custom users who have adequate training and experience and facilities and equipment to handle comparable quantities of material in other forms. It may also be reasonable to use such an approach to provide some flexibility in the case of calibration and

reference sources. It is anticipated that except for the R & D licensees, part 33 licensees, and certain custom users, one of the constraints would be that the sealed sources and devices are registered, as it is generally not practical for an applicant to supply adequate information to demonstrate that the radiation safety properties of unspecified sources or devices are inherently adequate to protect health and minimize danger to life and property.

The use of the SS & D registration process as a tool for licensing was intended to provide a more efficient and effective licensing process than to have all users provide detailed information about the sources and devices to be used, and for license reviewers to evaluate the safety of the sources and devices in conjunction with the evaluation of the applicant's training and experience and facilities and equipment. The changes proposed to §§ 30.32(g) and 32.210(g) are intended to further improve the efficiency and effectiveness of the licensing process by eliminating the need for unnecessary exemptions for recognized situations that are not unique to a particular applicant.

A.4 Extending Requirements Concerning Legacy Sources and Devices to All Byproduct Material Covered by Part 30

In the final rule published October 1, 2007 (72 FR 55863), which amended the Commission's regulations to incorporate the new categories of byproduct material added by the Energy Policy Act of 2005 (EPAct), a revision was made to § 30.32(g) to facilitate licensing the use of legacy sealed sources and devices. These are older sources and devices for which the manufacturer is no longer in existence and for which it may be impossible to provide all of the categories of information identified in § 32.210(c), as required by § 30.32(g)(2). Generally, that amendment was intended to cover sources and devices manufactured before the promulgation of § 32.210. This provision, in § 30.32(g)(3), delineates additional information that is required to license the use of a sealed source or device for which all of the information previously required is not available. The information must include a description of the source or device, a description of radiation safety features, intended use and associated operating experience, and results of a recent leak test. The NRC licensing staff will review the submitted information to make a licensing decision regarding possession and use of the source or device. However, that amendment limited the provision to sealed sources and devices containing naturally occurring and accelerator-produced radioactive material (NARM), because the scope of that rule was limited to such materials. There are, however, a number of legacy sealed sources and devices containing pre-EPAct byproduct material, i.e., byproduct material as defined in section 11e.(1) of the AEA, for which it may also be impossible to provide all of the information required under § 32.210(c). This rule proposes to extend that provision to legacy sources and devices containing any byproduct material, as defined in Part 30.

B. Establish a New Class Exemption for Certain Industrial Products

As noted in the introduction on regulatory framework, class exemptions allow the Commission to exempt categories of products or devices with similar characteristics and purposes, rather than requiring individual exemptions for each product. For example, the existing class exemption in § 30.20 for gas and aerosol detectors was established in April 1969. Since that time, new products possessing similar attributes were allowed to be licensed for distribution under § 30.20 as they were developed. This regulatory structure allowed the new detectors to be used without product-specific exemptions, which would have required additional rulemaking. The health and safety of the public is ensured by evaluating each specific product against safety criteria contained in the regulations that apply to all products in a class.

There are a number of products used under the general license in § 31.5 that could meet similar safety criteria but do not come under either of the existing classes, i.e., §§ 30.19 and 30.20. Certain industrial devices were identified by the NRC staff for possible use under an exemption from licensing requirements because of their low risk; i.e., static eliminators and ion generators containing polonium-210, beta backscatter and transmission devices, electron capture detectors for gas chromatographs, x-ray fluorescence analyzers, and calibration and reference sources. Dose assessments were conducted for these categories of products assuming use under an exemption from licensing and included in NUREG–1717. For each of the types of licensed products suggested for possible use under an exemption and included in the dose evaluations of NUREG–1717, some of the products clearly result in doses so low that requiring use under a license could be considered an unnecessary regulatory burden and an unnecessary expenditure of user and NRC resources. However, it is not clear that each type of device would necessarily qualify for exemption for all of the radionuclides and quantities used. Therefore, the NRC is proposing a new class exemption, rather than attempting to create a number of additional product-specific exemptions with appropriate limitations, such as radionuclide-specific quantity limits.

The new class exemption in proposed § 30.22, covering a broad range of industrial devices, would maintain protection of public health and safety and, at the same time, relieve regulatory burden. Presently, most of these products are licensed under the general license in § 31.5 and equivalent Agreement State regulations. In order for a product to be distributed for use under the new class exemption, the manufacturer or importer would be required to demonstrate that a particular device meets certain safety criteria, with NRC review and approval. Such a class exemption would also allow for the development of new products within the class or category of industrial devices that could be approved for use under exemption without the need for additional rulemaking to add product-specific exemptions.

This approach allows for a broader number of devices to be exempted and for variations on a product or new products in the class to be approved for use under exemption from licensing without further need for rulemaking. The exemption may lead to more devices being developed with appropriately low risk that could meet the criteria for the exemption. Thus, additional benefit to society may accrue if more people make use of the types of products in this class.

Although some calibration and reference sources are currently licensed under § 31.5, a clarification is included in the proposed exemption that such sources are not covered, since it is more difficult to assess likely scenarios of handling and use for sources not incorporated into a specific device with a specific purpose; in particular, the number of sources that might be used or stored in close proximity is apt to be greater and more uncertain. Also, calibration and reference sources are frequently used by persons using other radioactive materials under a license, minimizing the benefit of an exemption in this case. Many of these are already used under the exemption in § 30.18. Some containing americium-241 and radium-226 are also covered by the general license in § 31.8. Therefore, it is not believed that the type of exemption

being proposed is an appropriate regulatory approach for calibration and reference sources.

The proposed exemption would cover industrial devices with the same list of purposes as are covered by the general license in § 31.5 with the exception of that of producing light. The existing class exemption for self-luminous products is considered adequate and appropriate to provide for exempt use of products of this type.

The proposed exemption of industrial products would have a lower dose criterion for routine use than that associated with the general license and would include consideration of potential doses from disposal. Devices used under § 31.5 must be returned to a specific licensee, such as a vendor or waste broker, and ultimately disposed of as low-level radioactive waste. Under the proposed exemption from licensing requirements, there would be no controls on disposal; the devices would be disposed without regard to their radioactivity. Thus, the potential impacts of uncontrolled disposal would need to be evaluated in the licensing process for each particular device.

The proposed safety criteria are similar to the current criteria for licensing the manufacture or distribution of gas and aerosol detectors (contained in §§ 32.27 and 32.28). However, those criteria include more organ-specific limits, because they were based on the dose limitation methodology recommended by the International Commission on Radiation Protection (ICRP) in 1959 in ICRP–2, "Report of ICRP Committee II on Permissible Dose for Internal Radiation," whereas more recently developed approaches to radiation protection rely less on individual organ dose limits or constraints, particularly when doses are low, and include weighting organ dose contributions to overall dose. These newer approaches involve calculating doses in total effective dose equivalent as in 10 CFR part 20, based on ICRP–26, "Recommendations of the International Commission on Radiological Protection," or effective dose, based on the subsequent recommendations of the ICRP. The proposed safety criteria for the new class exemption would not require that the exposures be estimated specifically in terms of total effective dose equivalent (TEDE) or effective dose.

The intent is that generally the most up-to-date dose calculation methodology would be used, and that the approach would allow for future updates. However, the staff would normally accept the use of another method such as that now reflected in 10 CFR part 20, as long as it did not result in a significantly different level of safety.

The NRC notes that the ICRP issued its latest recommendations in ICRP–103, "The 2007 Recommendations of the International Commission on Radiological Protection." The specific dose conversion factors based on those recommendations have not yet been calculated. However, as the safety criteria for the class exemption are design criteria, it is preferable to have the flexibility to use the latest information on estimating risks.

For the purposes of these provisions, a definition of a generic term for internal dose, "committed dose," would be added to § 32.2 to encompass this approach, which includes weighting of organ doses, but not strictly under one system.

The proposed dose criterion for routine use of these devices is 200 μSv (20 mrem)/year, which is significantly higher than that for gas and aerosol detectors (5 mrem (50 μSv)/year). This exemption would cover industrial type devices, used almost exclusively on the job, meaning that routine doses will normally be occupational, i.e., doses received by individuals in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material. In a small proportion of cases, a user might not be a worker, but a student, for example. However, these instances are likely to involve a limited amount of time for exposure over the year, reducing doses to these types of users. Due to the industrial purpose of the devices, these products are not expected to be sold in the large quantities possible for consumer products, such as smoke detectors. Therefore, these products would contribute to the doses of many fewer people. Doses to members of the public would generally be smaller, usually much less than that to the user.

In order to provide reasonable assurance that members of the public are not routinely exposed to more than a few mrem/year (few 10's of μSv/year), the proposal would also include a criterion that the device is unlikely to be routinely used by members of the general public in a non-occupational environment. The Commission's policy for consumer products is for the general public to receive no more than a small fraction of the public dose limit from exempt products, so that their exposures from all sources are not likely to routinely exceed the public dose limit, which is now 100 mrem (1 mSv)/year.

The fact that industrial products are not as widely used as items commonly used in the home would tend to limit the contribution by these products to disposal doses; e.g., the exposures of landfill workers. Nonetheless, the proposal includes a separate criterion for disposal, 10 μSv (1 mrem)/year. This criterion is lower than the proposed criterion for routine use, because the same individuals are apt to be exposed to all products disposed in any particular landfill or municipal incinerator.

Accident criteria would be similar to those for products to be used under §§ 30.19 and 30.20. The higher of these limits, that for the lowest probability accident, is also used in the safety criteria for the general license in § 31.5, under which many of the devices potentially covered by the proposed new class exemption are currently used [§ 32.51(a)(2)(iii)]. However, the proposed safety criteria for the new class exemption include additional criteria to ensure that the radionuclide quantities allowed for use under the exemption are limited, such that the maximum possible dose is controlled, even if the circumstances leading to such a dose are extremely improbable.

The accident criteria currently in § 32.23(d), § 32.24, Column IV, § 32.27(c), § 32.28, Column III, and § 32.51(a)(2)(iii) were expected to limit the total amount of radioactive material likely to be approved for use under the relevant exemption or general license, irrespective of the design to contain or shield the material. However, designs to contain the material even under severe conditions of use or accident have resulted in relatively large quantities of materials being approved in some cases. Although the risk is well controlled by these designs, possible scenarios of misuse or malicious use are not required to be evaluated.

For this new exemption, a proposed criterion would require that specific scenarios of misuse be analyzed and shown to meet certain dose limits. The analysis required to meet this misuse criterion would be relatively simple. Evaluating actual risk from possible misuse or malicious use would be much more difficult, but such risks would be limited by this proposed criterion. The proposed criterion is 100 mSv (10 rem), plus an additional skin dose criterion. This criterion is slightly lower than the accident criterion of 15 rem (150 mSv) applicable to products covered by the existing class exemptions and the general license in § 31.5. The proposed criterion is considered to be a more appropriate value given the high level of uncertainty in estimates of doses under accident conditions.

Limiting the radionuclide quantities allowed for use under the exemption, even if well contained, has the additional benefits of: (1) Minimizing risks associated with devices becoming subject to scrap metal recycling, such as property damage due to contamination resulting from smelting; (2) further controlling overall impacts to waste disposal workers; (3) minimizing overall impacts to the environment from uncontrolled disposal of products used under exemptions from licensing; and (4) minimizing the potential problems of products exempted by NRC being detected at and sometimes rejected for disposal in landfills and municipal incinerators by State and local restrictions.

In addition, a fixed limit for radionuclides of concern for security, in terms of a small fraction of the Category 2 threshold as listed in Appendix E of Part 20 (which is based on the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources), is also included (in proposed § 32.30(c)(4)) to further ensure that the quantities of these radionuclides in exempt products are not such that they would be a practical source of obtaining radioactive materials in quantities sufficient to cause significant harm.

C. Remove Unnecessary Limitations From the Class Exemption for Gas and Aerosol Detectors

The class exemption in § 30.20 is for gas and aerosol detectors "designed to protect life or property from fires and airborne hazards." At the time that this exemption was added to the regulations, the applications of these types of devices under consideration were smoke detectors and devices to detect chemicals that would constitute an airborne hazard if inhaled. The words "designed to protect life or property from fires and airborne hazards" were included to ensure that the products provided a clear societal benefit. Products similar to those allowed, but not quite fitting the "class," cannot be approved for use under this exemption. For example, drug detectors were rejected for distribution for use under this exemption because they do not specifically protect life or property from fires or airborne hazards. The NRC believes that there is a clear societal benefit from this application and allowing its use under the exemption would be justified, as long as a particular device meets the applicable safety standards. A minor modification, therefore, is proposed to allow for a slightly broader class of product without eliminating the expectation of a societal benefit. "Designed to protect life or property from fires and airborne hazards" would be replaced with, "designed to protect health, safety, or property." This would allow other potential applications under an existing regulatory framework, which has safety criteria designed to adequately protect public health and safety.

D. Update the Regulations on Certain Static Eliminators and Ion Generating Tubes

Section 31.3 provides a general license for certain static eliminators and ion generating tubes. The static eliminators distributed for use under this provision include those intended for use by the general public. There are no requirements associated with this general license; however, the provision does not explicitly contain an exemption from parts 19, 20, and 21. Nonetheless, the Commission has generally treated products covered by this provision as if the users were exempt from licensing. Distribution must be authorized only by NRC and not by the Agreement States. There are no distribution requirements specified in part 32. Distributors are licensed under Part 30, with particular license conditions related to distribution determined on a case-by-case basis. Reporting requirements in licenses have been similar to exempt distribution reporting requirements.

This inconsistency results from the fact that the use of the static eliminators covered by this general license predated the regulations in 10 CFR parts 19, 20, 21, 30, and 32. The general license for static eliminators was first issued in part 30 in the 1950s shortly before the formalization of radiation protection requirements was completed by issuance of part 20. Therefore, the original general license did not include an exemption from part 20. Training requirements were separated from part 20 and issued in part 19 at a later date. The ion generating tubes covered by paragraph (d) of § 31.3 were also covered by the general license in part 30 prior to the recodification of byproduct material regulations into 10 CFR parts 30, 31, 32, 33, 34, 35, and 36 in 1965. The general licenses for byproduct material were moved from part 30 to part 31 at that time.

In 1971 (36 FR 6015; April 1, 1971), the Commission proposed to change this general license to an exemption, and also to expand it into a class exemption under which additional static elimination devices and ion generating tubes with differing radionuclides and quantities could be approved for use under the exemption through licensing actions. As a result of competing priorities for staff effort at the time, that rule was never finalized.

Although these products have a long history of use, there have been relatively few licensed distributors. Nonetheless, this situation has caused some confusion in the licensing process. The Commission is proposing to change this general license into an exemption from licensing in § 30.15(a)(2). The current licensed distributor would not be required to amend its license, but any future distributors would come under the distributor provisions associated with § 30.15; i.e., §§ 32.14, 32.15, and 32.16. This change is intended to have no effect on any current distributor or user of these products, only to remove an inconsistency in the regulations and to make any future licensing decisions in this regard more efficient and effective.

With respect to the issue of requirements for sealed source and device review, this change would remove the need for a registration certificate if these products are distributed under the authority of a license issued under § 32.14. The licensing practice of using the sealed source and device review and registration process for products to be used under the general license in § 31.3 primarily resulted from the lack of specific requirements for a distribution license in the regulations. Thus, § 32.210 provided the types of information to be provided concerning the product for NRC review.

E. Remove Prescriptive Requirements for Distributors of Generally Licensed Devices and Exempt Products

The Commission has determined that the requirements for manufacturers or initial distributors of exempt and generally licensed products are in some cases overly prescriptive, particularly in the areas of prototype testing and acceptance sampling/quality control (QC) procedures. The current prescriptive approach is easy to implement and regulate, but is relatively inflexible. When evaluating a new or redesigned product, the NRC requires prototype testing to validate the design of products and their ability to contain byproduct material. Acceptance sampling (a specific QC process) monitors the effectiveness of the manufacturing process for safety-significant parts to minimize the likelihood of failures and events caused by inadequate manufacturing quality.

This proposed rule is intended to focus the regulations on performance, rather than procedures. The regulations would retain general requirements and

provide general standards by which performance may be judged, rather than specifying detailed procedures that must be followed, except for products for which oversight of these activities would no longer be required as discussed under Section III.F., "Make the Requirements for Distributors of Exempt Products More Risk-Informed." The NUREG–1556 series of documents provides guidance to licensees and applicants on acceptable approaches to meeting these requirements.

The procedures included in the current regulatory requirements are generally acceptable to meet the proposed performance-based requirements. Safety benefits of the proposed changes in this area would primarily be gained indirectly by removing overly burdensome and possibly counterproductive procedures—and more importantly, by accommodating the use of new technologies. The intent is for the proposed regulatory requirements to be equivalent to the current practices (except as noted), so that existing licensees would not have to change their procedures as a result of this rulemaking. However, the provisions are written so that applicants and licensees would have flexibility in the methods that they use to determine the design quality (prototype tests) and manufacturing quality (acceptance sampling/QC) of these products. In keeping with international best manufacturing standards, manufacturers and the distributors that represent them are expected to maintain a quality management system that stresses continual improvement. Examples of such system requirements can be found in ISO 9001:2000, "Quality Management Systems—Requirements," and, unique to the nuclear safety field, IAEA Safety Series No. 50–C/SG–Q, "Quality Assurance for Safety in Nuclear Power Plants and Other Nuclear Installations, Code and Safety Guides Q1–Q14." While the focus of ISO 9001:2000 is on customer satisfaction, and the primary focus of the IAEA series is on nuclear facility safety, these documents contain some quality management concepts that are appropriate to the distribution of generally licensed and exempt products containing byproduct material.

Prototype Test Procedures

This rule proposes to simplify current prescriptive regulations for prototype testing for new products proposed for use under general license. The proposed provisions include only those aspects that are results-oriented, rather than specifying detailed procedures that must be followed. An applicant may choose to follow current prototype test procedures, as they would satisfy the outcomes required by this proposed rule in every situation. The specific procedures would be removed from the regulations and included as example acceptable procedures in guidance documents.

In the case of generally licensed products, regulations that contain prescriptive requirements for prototype testing are:

- Paragraph (d)(4) of § 32.53, "Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer," standard to pass tests described in § 32.101;
- Paragraph (d)(2) of § 32.57, "Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer," standard to pass tests described in § 32.102;
- Paragraph (e)(4) of § 32.61, "Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer," standard to pass tests described in § 32.103;
- Section 32.101, "Schedule B—prototype tests for luminous safety devices for use in aircraft";
- Section 32.102, "Schedule C—prototype tests for calibration or reference sources containing americium-241 or radium-226"; and
- Section 32.103, "Schedule D—prototype tests for ice detection devices containing strontium-90."

No prescriptive prototype testing requirements pertaining to manufacturers of exempt products remain in the regulations, as they have been previously removed. Most recently, §§ 32.14(d)(2) and 32.40 were removed by a rule published October 16, 2007 (72 FR 58473).

Acceptance Sampling and Quality Control Procedures

In the case of generally licensed products, regulations that contain prescriptive requirements for acceptance sampling/quality control procedures are:

- Paragraphs (a) though (d) of § 32.55, "Same: Quality assurance; prohibition of transfer" ("Same" refers to "Luminous safety devices for use in aircraft");
- Section 32.59, "Same: Leak testing of each source" ("Same" refers to "Calibration or reference sources containing americium-241 or radium-226");
- Paragraphs (a) through (e) of § 32.62, "Same: Quality assurance; prohibition of transfer" ("Same" refers to "Ice detection devices containing strontium-90"); and
- Section 32.110, "Acceptance sampling procedures under certain specific licenses."

The prescriptive requirements for acceptance sampling/quality control procedures pertaining to manufacturers of exempt products are paragraphs (a)(2), (a)(3), and (c)(2) of § 32.15, "Same: Quality assurance, prohibition of transfer, and labeling." ("Same" refers to "Certain items containing byproduct material.")

These all include specified procedures; §§ 32.15(a) and (c), 32.55(b) and (d), and 32.62(c) and (e) specifically refer to § 32.110.

The NRC intends to allow acceptance sampling to be performance-based, rather than specifying procedural details. Section 32.110 provides that a random sample shall be taken from each inspection lot of specified licensed devices for which testing is required in accordance with the appropriate sampling table in that section. If the number of defectives in the sample does not exceed the acceptance number in the appropriate sampling table, the lot shall be accepted, while if the number of defectives exceeds the acceptance number, the entire inspection lot shall be rejected. There is no longer a need for NRC to maintain the acceptance sampling tables in § 32.110, which provides the number of acceptable defective units in various lot sizes for a variety of Lot Tolerance Percent Defective values. **Note:** *Lot Tolerance Percent Defective* is defined in § 32.2 as the poorest quality in an individual inspection lot that should be accepted. The table in § 32.110(b)(6) Lot Tolerance Percent Defective 5.0 percent correlates with the standard in the above cited regulations. However, the other seven tables in § 32.110 apparently have been little used since their publication in 1974, as there are no specific standards in Part 32 requiring Lot Tolerance Percent Defectives other than 5 percent. Licensees can now easily use widely available computer software to determine their own acceptance sampling procedures to best monitor their manufacturing processes. This rule would remove § 32.110. Acceptance sampling criteria would continue to be specified in §§ 32.15, 32.55, and 32.62, specifying the values required for quality (Lot Tolerance Percent Defective) and confidence. Section 32.59 requires leak testing of each source for calibration or reference sources containing americium-241 or radium-226 generally licensed under § 31.8, rather than sampling of lots. This rule does not propose to change that

provision other than providing minor clarifications.

Presently, the NRC requires the affected categories of licensees to perform acceptance sampling in accordance with § 32.110 or propose alternative procedures (under § 32.15(b), § 32.55(c), or § 32.62(d)) which provide a Lot Tolerance Percent Defective of 5.0 percent at a consumer's risk of 0.10. This "consumer's risk" criterion is equivalent to 90 percent confidence that the Lot Tolerance Percent Defective will not be exceeded. The applicant's quality control procedures, including any alternate procedures proposed, are reviewed and approved by NRC. The proposed rule would not change the 5 percent criterion for Lot Tolerance Percent Defective (i.e., 95 percent acceptance). The current value of consumer risk of 10 percent is more relaxed than others used by NRC, such as in inspections, which use standards of no more than 5 percent defective at 5 percent risk. The proposed rule would revise the acceptance sampling standard to no more than 5 percent risk, expressed as "95 percent confidence," for those categories of products for which the acceptance criteria are specified in the regulations. The term "confidence" is now more commonly used in this context.

Most of NRC's statistical acceptance criteria today B such as in inspections B are, at least, 95 percent acceptance with 95 percent confidence. Raising the required confidence level from 90 percent to 95 percent may be an increase in burden, but is justified, because the current standard is inconsistent with other agency practices, as well as industry standards. However, it is expected that because of the nature of the products covered by these regulations, the lot sizes apt to be used, and other factors, the proposed revision is unlikely to change the approaches used by the limited number of current licensees under these provisions.

Another proposed change in NRC's acceptance sampling regulations is a clarification of the prohibition on the transfer of any defective lot. The prohibition of transfer of rejected *lots,* currently appearing in §§ 32.15(c)(2), 32.55(d)(2), and 32.62(e)(2), would be revised. Currently, the prohibition of transfer appears to apply only to individual items found to be defective, rather than addressing all items in a sampled lot that do not meet the acceptance standard. As proposed, these revisions concerning rejected lots would appear in §§ 32.15(b)(2), 32.55(d)(2), and 32.62(e)(2). From a statistical standpoint, unless a lot is sampled and tested in such a way as to demonstrate compliance with the required measures of quality assurance, the entire lot should be rejected. The proposed rule would require that distribution of any part, or sub-lot, of a rejected lot must be in accordance with procedures spelled out in the license, and that testing after repairs must be performed by an independent reviewer. The provision for an independent reviewer is a proposed new requirement, but it is an IAEA recommendation, and may have been used voluntarily as an industry best practice. IAEA recommends that, based on sound statistical theory, depending on the safety significance of the defective item or lot, the independent reviewer may be a different inspector from the one that performed the original sampling, or an inspector from a third party. In the case of the products for which these changes are being proposed, the risk is low and it is sufficient for the independent inspector to simply be another qualified employee. Individual worker accountability plays an important role in an effective quality assurance (QA) program, and an independent reviewer, besides adding another layer of assurance that the sub-lot or part is acceptable, would add accountability to the program.

The sampling plan will normally be detailed in the license, which will ensure that the quality assurance program is systematic and planned where justified, such as for lot sizes, sample sizes, criteria, and procedures. The primary source of current guidance on quality control and quality assurance is NUREG–1556, Volume 3, Rev. 1, "Consolidated Guidance About Materials Licenses, Applications for Sealed Source and Device Evaluation and Registration." This guidance indicates that NRC may accept a certificate of accreditation in lieu of a full set of QA/QC plans or procedures. The vendor providing certification must, however, make the commitment that the generic QA/QC program includes provisions which address the specific requirements in the regulations for the fabrication of the sealed sources or devices. Depending on the specific requirements of the fabrication process, such provisions would include:

- Verifying that the design conforms fully with the statements and commitments submitted in support of the application (including materials, dimensions within stated tolerances, manufacturing methods, assembly methods, labeling), using sampling methods that meet applicable provisions, such as § 32.55.
- Leak testing all units to 185 Bq (0.005 μCi).
- Testing all units for proper operation of all safety features.
- Verifying that, for all units, the radiation levels do not exceed the maximum values stated in the application.

The proper treatment and definition of lots is essential from a statistical perspective, and relevant to acceptance sampling procedures. For the purposes of acceptance sampling, a "lot" should consist of homogeneous products manufactured from the same or similar machines, interchangeable in terms of their intended use or function. Similarly, from a statistical perspective, a sampling plan must demonstrate certain characteristics to sufficiently guarantee quality: Manufacturer compliance with predetermined lot sizes, sample sizes, sampling methodology, and acceptance criteria; agreement with a one-time decision to accept or reject a lot in its entirety; separate, predetermined treatment of sub-lots; and the calculation and reporting of separate measures for quality and for confidence. It should be emphasized, however, that the regulatory requirement for acceptance sampling is not an attempt to control overall product quality, but to minimize the possibility that a distributed product has inadequate or malfunctioning safety features.

In summary, this proposed rule would revise the cited paragraphs concerning prototype testing and quality control, including specific sampling requirements, to make these requirements for distributors more flexible and performance-based rather than prescriptive. Guidance on quality assurance methods is included in NUREG–1556, Volume 3, Revision 1, including specifically Appendix G.

Less prescriptive, more flexible, performance-based regulations would continue to specify performance requirements. Generally, the specific procedures being removed from the regulations would continue to be considered acceptable. The NRC normally evaluates products using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, NRC formulates reasonable standards and criteria in consultation with the manufacturer or distributor. References to appropriate industry and consensus standards are included in NUREG–1556, Volume 3, Rev. 1, Appendix F. Updated guidance would be provided when a new or revised industry standard becomes available that NRC considers more

appropriate. The licensee would be free to propose alternative methods to those presented in industry standards and guidance, provided that the methods provide sufficient evidence that all safety related components are capable of performing their intended functions.

Current licensees would need to make any necessary upgrade to their QC programs when the rule becomes effective. However, because license conditions are written broadly, it is not expected that any such changes in the QC program would be inconsistent with an existing license (or registration certificate). Any changes needed in the license to better ensure consistency with the revised requirements would likely be made at the time of the next license renewal or related amendment of the license.

F. Make the Requirements for Distributors of Exempt Products More Risk-Informed

To a large extent, NRC applies similar requirements throughout Part 32 on manufacturers and distributors of all categories of products, irrespective of the quantity of byproduct material within or the risk of a product. However, given the low risk of some exempt products, some of the existing requirements may be unnecessary, and not commensurate with the associated risk. This is particularly true in the areas of prototype testing and quality control requirements for products to be used under exemptions from licensing.

The NRC considered whether some of the products used under an exemption from licensing present such low levels of radiation exposures, both routinely and in the event of accidents, that continued NRC oversight of the specific prototype tests and/or the quality control/quality assurance to be applied by the manufacturer or distributor would not be warranted.

Although many products distributed under the class exemptions would likely meet such a low-risk standard, the Commission does not believe it prudent to eliminate any of these requirements for the class exemptions. The safety criteria for each class exemption are intended to ensure that the risks associated with any product approved for use under the associated exemption are quite low. Nonetheless, because of the nature of a class exemption to allow for new products to be approved, it is not possible to conclude that elimination of oversight of prototype testing or quality control procedures for an entire class of products is prudent. The evaluation of the safety of the individual product may depend on knowledge of such procedures.

Although it may be possible to develop an explicit approach to allow for removal of oversight of these types of procedures for some of the products distributed under the class exemptions, the burden of these requirements is not so great that the effort to develop a specific procedure for this did not seem worthwhile. Applicants and licensees do nonetheless have the option to seek an individual specific exemption under § 30.11 from any requirement applicable to the use of byproduct material.

The NRC evaluated the inherent potential for radiation exposures from products containing byproduct material used under product-specific exemptions and the likelihood of increases in risks if oversight of the subject procedures were removed. The product-specific exemptions appear in § 30.15. There are currently four types of products listed in that provision for which future distribution is allowed, specifically timepieces, ionization chamber smoke detectors, electron tubes, and ionizing radiation measuring instruments. (Note that in the discussion under Section III.D., "Update the Regulations on Certain Static Eliminators and Ion Generating Tubes," the Commission is proposing to add another exemption to § 30.15.) The requirements of this type for manufacturers and distributors of products used under § 30.15 are contained in: § 32.14(b)(4), on submittal of information on prototype test procedures used and the results; § 32.14(b)(5), on submittal of quality control procedures to be used; and §§ 32.15(a)(2) and (a)(3) and 32.110, on specific sampling procedures for quality control. Paragraph 32.15(c) also contains a prohibition on transferring any defective lot or item to exempt persons.

Even without NRC's continuing oversight of these procedures, licensees would be motivated to retain them as good business practices. There are a number of factors that would likely cause manufacturers and distributors to continue to conduct prototype testing and at least some form of quality control/assurance. In some cases, functionality testing closely aligns with testing for containment of radioactive material. The consideration of risk for these products, however, did not rely on this expectation, beyond some reasonable bounding assumptions about the likelihood and consequences of distributing defective products. For example, failures that result in functional failure may happen more frequently, but it is not reasonable to assume that manufacturers would continue to distribute a large percentage of defective devices over long periods.

The NRC used NUREG–1717 as a primary resource concerning estimates of doses that result from the distribution, use, maintenance and repair, disposal, and accidents involving these products. The NRC considered the extent to which these doses might be affected if the lack of oversight over prototype testing resulted in a product design that was less effective in containing or shielding the byproduct material. The NRC also considered the extent that doses or probability of accidents could be affected if the lack of oversight of quality control/quality assurance significantly reduced the effectiveness of licensees' programs in this area. This assessment was semi-qualitative as there is no data available on products used without regulatory control, which could support a quantitative probabilistic risk assessment.

This proposed rule would eliminate NRC oversight for these types of activities for a few of the exempt products as not justified, based on risk. Requirements to submit information on prototype tests in § 32.14(b)(4) would be eliminated for products exempt under § 30.15(a)(7) and (8), ionization chamber smoke detectors and electron tubes respectively. This requirement would also be eliminated for timepieces under § 30.15(a)(1) containing promethium-147 or tritium in the form of gaseous tritium light sources. Oversight of quality control/quality assurance would be eliminated for these same products as well as for products to be used under the new exemption in § 30.15(a)(2), static eliminators and ion generating tubes formerly covered by the general license in § 31.3. This is in a proposed revised § 32.14(b)(5), which would require that quality control procedures be submitted for approval only for ionizing radiation measuring instruments and timepieces containing tritium in the form of paint. Other requirements in the application for a license to distribute these products would remain, such as the submittal (under § 32.14(b)) and evaluation (§ 32.14(d)) of basic design features intended to contain the byproduct material.

Based on the assessment of the inherent safety of these products, it is estimated that even if a lack of appropriate prototype testing resulted in lower quality product designs in the future or poor quality control resulted in degradation of production quality, the potential increases in individual doses would be less than 10μSv (1 mrem)/year in any situation where significant numbers of products could be affected. Also, in the extreme case of a significant

change in future distributor behavior, some individual doses could be increased by somewhat higher amounts in non-routine situations. Overall, considering both potential increases in doses and the probability of circumstances resulting in those increases, the potential incremental risk is estimated to be insignificant.

Unnecessary regulatory burden on distributors of these products would be reduced. Because, as noted above, licensees are not likely to eliminate such procedures as a result of discontinued NRC oversight, the benefits assumed are only those associated with eliminating the submittal of testing/sampling procedures for review and approval, eliminating the submittal of prototype testing results, and allowing added flexibility to change procedures in response to other factors, including competitive demands for continuous quality improvement, without NRC permission.

Current licensees authorized to distribute products affected by this change would need to amend their license in order to not be held accountable for continuing to follow the QC/QA program as delineated in their license. This would be a simple amendment as the regulations would be clear that this license condition is no longer required.

The NRC does not currently believe that any similar requirements for submitting information on such procedures for generally licensed devices are candidates for revocation based on risk, as the safety of these devices generally relies on the design and manufacturing process quality to a greater degree than for these exempt products. This is less so in the case of calibration and reference sources used under § 31.8 and the risk directly associated with these sources may be sufficiently low to consider removing oversight of prototype testing or quality control, particularly given the general license's applicability only to specifically licensed persons. However, problems with leakage or significant variation of quantities would affect the use of these sources so as to indirectly affect health and safety of other activities.

G. Specific Questions for Comment

The NRC invites comments on any aspect of this proposed rule, but has these specific questions for consideration:

1. Updating of registration certificates in the SS & D Registry (Discussed in Section III. A.2):

(a) Under what circumstances should proposed § 32.210(h) be used to require a reevaluation? How should such a reevaluation be conducted with minimum impact to industry?

(b) How might registration certificates best be updated so as not to discourage improvement in the design of sources or devices, more readily allow for the application of updated industry standards, and ensure that information in the certificates is fully consistent with current practices? (For example, in addition to the proposed provision in § 32.210(h), other options could include reviewing certificates at the time of license renewal, in part or in whole; adding separate expiration dates to certificates with typically longer terms than licenses, e.g., 10 to 20 years; and explicitly allowing licensees to make changes without NRC approval, if these changes do not reduce safety margins.)

(c) How should certificates for previously approved devices be handled if the device does not meet current standards, such as in the case of the separately proposed (August 3, 2009; 74 FR 38372) quantity limit in the general license in § 31.5 (and comparable Agreement State provisions)? How should registration certificates be handled in this situation? (For example, in some cases, the distributor may be able to limit the quantity of affected radionuclides, rather than change its certificate to one for specifically licensed devices.)

(d) In general, how might the NRC use the proposed provision for review in § 32.210(h) in relation to changes in standards for products or limits in addressing continued distribution and the timing for changes to the authority to distribute tied to the registration certificate?

2. New class exemption for industrial products in § 30.20 (Discussed in Section III. B.):

(a) Is the 20 mrem/year routine dose criterion appropriate, given that users are workers, but there is no control of conditions of use once a product is distributed for use under an exemption from license?

(b) Would it be appropriate to apply certain aspects of the proposed standards for this class exemption to the safety criteria (§§ 32.23 and 32.27) for the existing class exemptions (§§ 30.19 and 30.20), namely, the use of more up-to-date methodology for dose assessment as reflected in the proposed definition of the term "committed dose," the inclusion of a misuse scenario and/or a specific quantity limit to control quantities that may meet the safety criteria when a source is well contained and shielded, and the consideration of the number of products likely to accumulate in one place in the dose assessments for all scenarios?

3. Expanding the class exemption for gas and aerosol detectors in § 30.20 by revising the requirement of "designed to protect life or property from fires and airborne hazards" to instead be "designed to protect health, safety, or property" (Discussed in Section III. C.):

(a) Are there additional products that may be exempted under this expanded definition of the class not specifically considered by the NRC?

(b) Are these words adequate to ensure that products present a clear societal benefit?

(c) Are there any potential problems with approving additional products for use under this exemption and later reevaluating the safety criteria associated with this exemption for potential alignment with newer recommendations of the ICRP?

4. Changes to certain quality control requirements in §§ 32.15, 32.55, and 32.62 to (i) raise the statistical acceptance criteria; i.e., increasing the required confidence that the Lot Tolerance Percent Defective will not be exceeded from the current 90 percent (consumer risk of 0.10) to 95 percent; and (ii) require that distribution of any part, or sub-lot, of a rejected lot must be in accordance with procedures spelled out in the license and that testing after repairs must be performed by an independent reviewer (Discussed in Section III. E.). These proposed revisions are in § 32.15(a) and (b) for certain exempt items, § 32.55(b) and (d) for luminous safety devices used in aircraft, and § 32.62(c) and (e) for ice detection devices.:

(a) Would any actual changes in practice need to be made by affected licensees? The NRC would welcome information that would aid in evaluating any impact.

(b) Would there be any impact on manufacturers or distributors of products for which oversight of quality control practices are proposed to be removed, if the new provisions were applied to these products instead, i.e., if all of the exceptions in § 32.14(b)(5) were not made effective as proposed? (As discussed under Section III. F. "Make the Requirements for Distributors of Exempt Products More Risk-Informed," products for which quality control oversight may be removed are: Ionization chamber smoke detectors, electron tubes, and timepieces containing promethium-147 or tritium in the form of gaseous tritium light sources, covered by exemptions in § 30.15, and for products to be used under the proposed new exemption in

§ 30.15(a)(2), static eliminators and ion generating tubes formerly covered by the general license in § 31.3.)

5. Proposal in § 30.32(g)(5) to allow some licenses to specify only constraints on the number and type of sealed sources and devices to be used and the conditions under which they are to be used (Discussed in Section III. A.3):

(a) In view of the expectation that this authorization would only be granted in limited situations and due to special circumstances, how can NRC make it clear that approval of this approach would be at the NRC's discretion, rather than this being an open-ended option for anyone, or should the regulation specify when this approach is acceptable?

(b) Are there other situations besides those discussed, when identifying all of the sealed sources and devices to be licensed is particularly impractical?

H. Minor Clarifying or Administrative Revisions

Other minor revisions are proposed to better organize, clarify, or update the regulations in these parts, such as the renaming of subparts C and D and the movement of §§ 32.72 and 32.74 from subpart B to subpart C. These two sections would be moved because they do not cover generally licensed items. Minor conforming amendments are included in Parts 40 and 70 because the delineation of the delegation of licensing programs to the Regions is written broadly in these parts. All such revisions are noted in the following section.

IV. Summary of Proposed Amendments by Section

10 CFR 30.6(b)(1)(iv)—Would add a reference to new 10 CFR 32.30 as a licensing category not delegated to the NRC Regions.

10 CFR 30.15(a)(2)—Would add an exemption for certain static eliminators and ion generators in place of the general license in 10 CFR 31.3.

10 CFR 30.19(b)—Would clarify that applicants under 10 CFR 32.22 should also apply for a registration certificate.

10 CFR 30.20—Would slightly expand the class of products covered under this exemption from licensing; would clarify that applicants under 10 CFR 32.26 should also apply for a registration certificate; would update parts of the regulations from which persons are exempt to include 10 CFR Part 19.

10 CFR 30.22—Would establish a new class exemption for industrial devices initially transferred from 10 CFR 32.30 licensees.

10 CFR 30.32(g)(3)—Would extend the provision for providing alternative information on NARM legacy sealed sources and devices to all legacy sealed sources and devices.

10 CFR 30.32(g)(4)—Would add a provision for providing limited information for certain calibration and reference sources.

10 CFR 30.32(g)(5)—Would add a provision to allow for constraints on the number and type of sealed sources and devices to be used and the conditions under which they are to be used rather than requiring complete identification of all sealed sources and devices to be licensed.

10 CFR 30.38—Would add an explicit provision for amendment of registration certificates.

10 CFR 30.39—Would add registration certificates to clarify that the same requirements are applicable to amendment of a registration certificate as for issuance of a new certificate.

10 CFR 30.61—Would add registration certificates to provisions for modification and revocation of licenses and update reference to Parts under which licenses are issued.

10 CFR 31.3—General license would be removed, section reserved, and replaced by a new exemption in 10 CFR 30.15(a)(2).

10 CFR 31.23—Would remove reference to 10 CFR 31.3 and make other minor corrections.

10 CFR 32.1—Would expand the description of the scope of 10 CFR Part 32 to cover additional requirements and make clarifications.

10 CFR 32.2—Would add definitions of "committed dose" and "sealed source and device registry."

10 CFR 32.8—Would add to the list of information collection requirements: 10 CFR 32.30 on application requirements for distributors of exempt industrial devices, 10 CFR 32.31 on safety criteria to be addressed in the application for license under 10 CFR 32.30, 10 CFR 32.32 on reporting and recordkeeping requirements for distributors of exempt industrial devices, and 10 CFR 32.211 on requesting inactivation of registration certificates.

10 CFR 32.14(b)(4)—Would make exceptions to prototype testing requirements.

10 CFR 32.14(b)(5)—Would make exceptions to quality control requirements.

10 CFR 32.15(a), (b), and (c)—Would remove the specific procedural requirements for quality assurance, revise the acceptance criterion, and limit these requirements to products for which such procedures would be required under 10 CFR 32.14.

10 CFR 32.22—Would add an explicit requirement for sealed source and device registration.

10 CFR 32.26—Would revise the introductory text to expand the limitation of "from fires or airborne hazards," for the purpose of the detectors, thus, expanding the class of products covered; and would add an explicit requirement for sealed source and device registration.

10 CFR 32.30—Would establish requirements for an application to manufacture, process, produce, or initially transfer for sale or distribution exempt industrial devices.

10 CFR 32.31—Would establish safety criteria for approving industrial devices to be distributed for use under 10 CFR 30.22 and equivalent Agreement State regulations.

10 CFR 32.32—Would establish specific conditions of license for distribution of exempt industrial devices, including quality control, labeling, and reporting and recordkeeping requirements.

10 CFR 32.51(a)(6)—Would add an explicit requirement for sealed source and device registration for devices to be transferred for use under 10 CFR 31.5 and equivalent Agreement State regulations.

10 CFR 32.53—Would remove the reference to 10 CFR 32.101 and add requirements for prototype testing without details of procedures to be followed; would revise the requirement for information to be submitted on quality control/quality assurance to be consistent with less prescriptive approach in 10 CFR 32.55; would add an explicit requirement for sealed source and device registration.

10 CFR 32.55—Would revise the requirement to conduct quality assurance to be clearer and less prescriptive and revise the acceptance criterion.

10 CFR 32.56—Would add ATTN: GLTS to address for reporting, explicitly require reports to Agreement States, and clarify the need for reporting even if no transfers were made during the reporting period.

10 CFR 32.57(d)(2) and (e)—Would remove reference to 10 CFR 32.102 and add less prescriptive requirement for prototype testing in paragraph (e).

10 CFR 32.59—Would make minor clarifying amendments to testing requirements for calibration and reference sources to be used under 10 CFR 31.8 and equivalent Agreement State regulations.

10 CFR 32.61(e)(4) and (f)—Would revise the prototype test requirement by removing reference to 10 CFR 32.103 and adding less prescriptive

requirement for prototype testing in paragraph (f).

10 CFR 32.61(g)—Would add an explicit requirement for sealed source and device registration.

10 CFR 32.62(c), (d), and (e)—Would revise and clarify quality assurance requirements, acceptance criterion, and associated prohibition of transfer.

Heading of Subpart C would be changed to "Specifically Licensed Items."

10 CFR 32.72 and 10 CFR 32.74 would be moved from Subpart B to renamed Subpart C.

10 CFR 32.74(a)(4)—Would add an explicit requirement for sealed source and device registration for sealed sources and devices for medical use.

10 CFR 32.101—Specific prototype test procedures for luminous safety devices for use in aircraft would be removed.

10 CFR 32.102—Specific prototype test procedures for calibration and reference sources containing americium-241 or radium-226 would be removed.

10 CFR 32.103—Specific prototype test procedures for ice detection devices containing strontium-90 would be removed.

10 CFR 32.110—Specific acceptance sampling procedures would be removed.

Heading of Subpart D would be changed to "Sealed Source and Device Registration."

10 CFR 32.201—Would be moved from Subpart D to renamed Subpart C.

10 CFR 32.210(a) and (e)—Would remove restriction of applicability to specifically licensed items.

10 CFR 32.210(b)—Would add ATTN: SSDR to address for requests.

10 CFR 32.210(d)—Would add reference to other criteria which apply to various categories of sealed sources and devices.

10 CFR 32.210(g)—Would add criteria for sources and devices not requiring SS & D registration.

10 CFR 32.210(h)—Would add an explicit provision for additional review of registration certificates.

10 CFR 32.211—Would add an explicit provision for inactivation of sealed source and device registration certificates.

10 CFR 32.303(b)—Would add reference to new requirements not issued under section 223 of the AEA, as well as correct previous omissions.

10 CFR 40.5(b)(1)(iv)—Would add reference to new 10 CFR 32.30 as a licensing category not delegated to the NRC Regions.

10 CFR 70.5(b)(1)(iv)—Would add reference to new 10 CFR 32.30 as a licensing category not delegated to the NRC Regions.

V. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act (AEA), the Commission is proposing to amend 10 CFR parts 30 and 32 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

VI. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), NRC program elements (including regulations) are placed into compatibility categories A, B, C, D, NRC or adequacy category Health and Safety (H&S). Compatibility Category A are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner in order to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a national basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C, above, and, thus, do not need to be adopted by Agreement States for purposes of compatibility. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to the Agreement States under the Atomic Energy Act of 1954, as amended, or provisions of Title 10 of the Code of Federal Regulations (CFR). These program elements should not be adopted by the Agreement States. H&S are program elements that are required because of a particular health and safety role in the regulation of agreement material within the State and should be adopted in a manner that embodies the essential objectives of the NRC program.

The proposed rule would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. The proposed compatibility categories are designated in the following table:

COMPATIBILITY TABLE

Section	Change	Subject	Compatibility	
			Existing	New
30.6(b)(1)(iv)	Amend	Communications	D	D
30.15(a)(2)	Add	Certain items containing byproduct material		B
30.19(b)	Amend	Self-luminous products containing tritium, krypton-85, or promethium-147.	B	B
30.20	Amend	Gas and aerosol detectors containing byproduct material	B	B
30.22	New	Certain industrial devices		B
30.32(g)(3)	Amend	Application for specific licenses	C	C
30.32(g)(4)	Add	Application for specific licenses		C
30.32(g)(5)	Add	Application for specific licenses		C
30.38	Amend	Application for amendment of licenses and registration certificates.	D	D
30.39	Amend	Commission action on applications to renew or amend	D	D
30.61	Amend	Modification and revocation of licenses and registration certificates.	D	D

COMPATIBILITY TABLE—Continued

Section	Change	Subject	Compatibility	
			Existing	New
31.3	Remove	[Existing title—Certain devices and equipment]	B	★
31.23(b)	Amend	Criminal penalties	D	D
32.1(a)	Amend	Purpose and scope	D	D
32.2	Add	Definition: Committed dose		NRC
32.2	Add	Definition: Sealed source and device registry		D
32.8(b)	Amend	Information collection requirements: OMB approval	D	D
32.14(b)(4) and (b)(5)	Amend	Certain items containing byproduct material; requirements for license to apply or initially transfer.	NRC	NRC
32.15(a), (b), and (c)	Amend	Same: Quality assurance, prohibition of transfer, and labeling.	NRC	NRC
32.22(a)(3)	Add	Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer.	NRC	NRC
32.26	Amend	Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.	NRC	NRC
32.30	New	Certain industrial devices containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.		NRC
32.31	New	Certain industrial devices containing byproduct material: Safety criteria.		NRC
32.32	New	Conditions of licenses issued under § 32.30: Quality control, labeling, and reports of transfer.		NRC
32.51(a)(6)	Add	Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture, or initially transfer.		B
32.53(b)(5) and (d)(4)	Amend	Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer.	B	B
32.53(e) and (f)	Add	Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer.	B	B
32.55	Amend	Same: Quality assurance, prohibition of transfer	B	B
32.56	Amend	Same: Material transfer reports	B	B
32.57(d)(2)	Amend	Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer.	B	B
32.57(e)	Add	Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer.	B	B
32.59	Amend	Same: Leak testing of each source	B	B
32.61(e)(4)	Amend	Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer.	B	B
32.61(f) and (g)	Add	Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer.		B
32.62(c), (d), and (e)	Amend	Same: Quality assurance; prohibition of transfer	B	B
32.74(a)(4)	Add	Manufacture and distribution of sources or devices containing byproduct material for medical use.		B
32.101	Remove	[Existing title—Schedule B—prototype tests for luminous safety devices for use in aircraft].	B	★
32.102	Remove	[Existing title—Schedule C—prototype tests for calibration or reference sources containing americium-241 or radium-226].	B	★
32.103	Remove	[Existing title—Schedule D—prototype tests for ice detection devices containing strontium-90].	B	★
32.110	Remove	[Existing title—Acceptance sampling procedures under certain specific licenses].	B	★
32.210(a), (b), (d), and (e)	Amend	Registration of product information	B ★★	B ★★
32.210(g) and (h)	Add	Registration of product information		B ★★
32.211	New	Inactivation of certificates of registration of sealed sources and devices.		B ★★
32.303(b)	Amend	Criminal penalties	D	D
40.5(b)(1)(iv)	Amend	Communications	D	D
70.5(b)(1)(iv)	Amend	Communications	D	D

★ Denotes regulations that are designated Compatibility Category B but which will be removed from the regulations as a result of these proposed amendments. Agreement States should remove these provisions from their regulations when the regulations become final.

★★ D—for States that do not perform SS & D evaluations.

VII. Plain Language

The Presidential Memorandum "Plain Language in Government Writing" published June 10, 1998 (63 FR 31883), directed that the Government's documents be in clear and accessible language. The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the **ADDRESSES** heading.

VIII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC would make the requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up to date. The Commission is also proposing to redefine categories of devices to be used under exemptions, add explicit provisions regarding the sealed source and device registration process, and add flexibility to the licensing of users of sealed sources and devices. This action does not constitute the establishment of a standard that establishes generally applicable requirements. However, the regulations being amended concerning sealed source and device reviews, in particular § 32.210(d), would continue to indicate that the NRC uses accepted industry standards, if applicable, in its evaluations.

IX. Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended (NEPA), and the Commission's regulations in subpart A of 10 CFR Part 51, not to prepare an environmental impact statement for this proposed rule because the Commission has concluded on the basis of an environmental assessment that this proposed rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment. The following is a summary of the Environmental Assessment: Many of the individual actions being proposed are the type of actions described in the categorical exclusions of §§ 51.22(c)(2) and 51.22(c)(3)(i) and (iii). In addition, the proposed rule would remove prescriptive procedural provisions, add a new class exemption and a new product-specific exemption, broaden an existing class exemption, add flexibility to the basis for licensing the use of sealed sources and devices, and remove some requirements for the distributors of low risk exempt products. The Commission has concluded that none of these actions would have significant impacts to the environment or otherwise include any condition requiring consultation under section 102(2)(C) of NEPA.

The determination of this Environmental Assessment is that there will be no significant impact to the public from this action. However, the general public should note that the NRC welcomes public participation. Comments on any aspect of the Environmental Assessment may be submitted to the NRC as indicated under the **ADDRESSES** heading.

The NRC has sent a copy of the Environmental Assessment and this proposed rule to every State Liaison Officer and requested their comments on the Environmental Assessment. The Environmental Assessment may be examined on *http://www.regulations.gov* and at the NRC Public Document Room, O–1F21, 11555 Rockville Pike, Rockville, MD 20852. Single copies of the Environmental Assessment may be obtained from Catherine R. Mattsen, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone 301–415–6264, e-mail, *Catherine.Mattsen@nrc.gov.*

X. Paperwork Reduction Act Statement

This proposed rule would contain new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*). This proposed rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

Type of submission, new or revision: Revision.

The title of the information collection: 10 CFR Parts 30, 31, 32, 40, and 70, Requirements for Distribution of Byproduct Material, Proposed Rule

The form number if applicable: NRC Form 313

How often the collection is required: One time; annual; and occasional.

Who will be required or asked to report: Applicants and licensees who manufacture or initially distribute sealed sources and devices, and some users of those sources and devices.

An estimate of the number of annual responses: 58 [(10 CFR part 32—37 responses + 6 recordkeepers) + (NRC Form 313—15 responses)]

The estimated number of annual respondents: 44 (25 NRC licensees + 19 Agreement State licensees)

An estimate of the total number of hours needed annually to complete the requirement or request: 951 hours [10 CFR Part 32—957 (351 reporting + 606 recordkeeping) + (NRC Form 313—decrease of 6 hours reporting)]

Abstract: The NRC is proposing to amend its regulations to make requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up to date. The Commission is also proposing to redefine categories of devices to be used under exemptions, add explicit provisions regarding the sealed source and device registration process, and add flexibility to the licensing of users of sealed sources and devices. This action is primarily intended to make licensing processes more efficient and effective. These changes would affect manufacturers and distributors of sources and devices containing byproduct material and future users of some products currently used under general or specific license.

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the burden estimate accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the OMB clearance package may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1F21, Rockville, MD 20852. The OMB clearance package and rule are available at the NRC World Wide Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html* for 60 days after the signature date of this notice.

Send comments on any aspect of these proposed regulations related to information collections, including suggestions for reducing the burden and on the above issues, by July 26, 2010, to Information Services Branch (T–5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by Internet electronic mail to

Infocollects.Resource@NRC.gov, and to Christine J. Kymn, Desk Officer, Office of Information and Regulatory Affairs, NEOB–10202 (3150–0017, 3150–0001, and 3150–0120), Office of Management and Budget, Washington, DC 20503. Comments on the proposed information collections may also be submitted via the Federal eRulemaking Portal *https://www.regulations.gov,* Docket No. NRC–2008–0338. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. You may also e-mail comments to *Christine_J._Kymn@omb.eop.gov* or comment by telephone at (202) 395–4638.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XI. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission.

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the **ADDRESSES** heading. The analysis is available for inspection on *http://www.regulations.gov* and in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852. Single copies of the Regulatory Analysis may be obtained from Catherine R. Mattsen, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone 301–415–6264, e-mail, *Catherine.Mattsen@nrc.gov.*

XII. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule would not, if promulgated, have a significant economic impact on a substantial number of small entities. A significant number of the licensees affected by this action would meet the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121. However, none of the proposed revisions to the regulatory program would result in a significant economic impact on the affected entities.

XIII. Backfit Analysis

The NRC's backfit provisions are found in the regulations at §§ 50.109, 52.39, 52.63, 52.83, 52.98, 52.145, 52.171, 70.76, 72.62, and 76.76. The requirements contained in this proposed rule do not involve any provisions that would impose backfits on nuclear power plant licensees as defined in 10 CFR parts 50 or 52, or on licensees for gaseous diffusion plants, independent spent fuel storage installations or special nuclear material as defined in 10 CFR parts 70, 72 and 76, respectively, and as such a backfit analysis is not required. Therefore, a backfit analysis need not be prepared for this proposed rule to address these classes of entities. With respect to licenses issued under parts 30, 31, and 32, the NRC has determined that there are no applicable provisions for backfit. Therefore, a backfit analysis need not be prepared for this proposed rule to address parts 30, 31, or 32 licensees.

List of Subjects

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 31

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment.

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Criminal penalties, Government contracts, Hazardous materials transportation, Nuclear materials, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 70

Criminal penalties, Hazardous materials transportation, Material control and accounting, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR parts 30, 31, 32, 40, and 70.

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for part 30 continues to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

Section 30.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. In § 30.6, paragraph (b)(1)(iv) is revised to read as follows:

§ 30.6 Communications.

* * * * *

(b) * * *

(1) * * *

(iv) Distribution of products containing radioactive material to persons exempt under §§ 32.11 through 32.30.

* * * * *

3. In § 30.15, paragraph (a)(2) is added to read as follows:

§ 30.15 Certain items containing byproduct material.

(a) * * *

(2)(i) Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device.

(ii) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

(iii) Such devices authorized before (insert effective date of this rule) for use under the general license then provided in § 31.3 and equivalent regulations of

Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Commission.

* * * * *

4. In § 30.19, paragraph (b) is revised to read as follows:

§ 30.19 Self-luminous products containing tritium, krypton-85, or promethium-147.

* * * * *

(b) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under paragraph (a) of this section, should apply for a license under § 32.22 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.

* * * * *

5. Section 30.20 is revised to read as follows:

§ 30.20 Gas and aerosol detectors containing byproduct material.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, 21, and 30 through 36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect health, safety, or property, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.26 of this chapter, which license authorizes the initial transfer of the product for use under this section.

(b) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use under paragraph (a) of this section, should apply for a license under § 32.26 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.

6. Section 30.22 is added under the undesignated heading Exemptions to read as follows:

§ 30.22 Certain industrial devices.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, 21, 30 through 36, and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.30 of this chapter, which license authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(b) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under paragraph (a) of this section, should apply for a license under § 32.30 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.

7. In § 30.32, paragraph (g)(3) is revised and paragraphs (g)(4) and (g)(5) are added to read as follows:

§ 30.32 Application for specific licenses.

* * * * *

(g) * * *

(3) For sources or devices manufactured before (insert effective date of this rule) that are not registered with the Commission under § 32.210 of this chapter or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in § 32.210(c) of this chapter, the applicant must provide:

(i) All available information identified in § 32.210(c) of this chapter concerning the source, and, if applicable, the device; and

(ii) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test; or

(4) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with § 32.210(g)(1) of this chapter, the applicant may supply only the manufacturer, model number, and radionuclide and quantity; or

(5) Propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, as an alternative to identifying each sealed source and device individually.

* * * * *

8. Section 30.38 is revised to read as follows:

§ 30.38 Application for amendment of licenses and registration certificates.

Applications for amendment of a license shall be filed on Form NRC–313 in accordance with § 30.32 and shall specify the respects in which the licensee desires its license to be amended and the grounds for the amendment. Applications for amendment of sealed source and device registration certificates shall be filed in accordance with § 32.210 of this chapter and any other applicable provisions and shall specify the respects in which the licensee desires its certificate to be amended and the grounds for the amendment.

9. Section 30.39 is revised to read as follows:

§ 30.39 Commission action on applications to renew or amend.

In considering an application to renew or amend a license or to amend a sealed source or device registration certificate, the Commission will apply the applicable criteria set forth in § 30.33 and parts 32 through 36 and 39 of this chapter.

10. Section 30.61 is revised to read as follows:

§ 30.61 Modification and revocation of licenses and registration certificates.

(a) The terms and conditions of each license and registration certificate issued under the regulations in this part and parts 31 through 36 and 39 of this chapter shall be subject to amendment, revision, or modification by reason of amendments to the Act, or by reason of rules, regulations, and orders issued in accordance with the terms of the Act.

(b) Any license or registration certificate may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under section 182 of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means that would warrant the Commission to refuse to grant a license

or registration certificate on an original application, or for violation of, or failure to observe any of the terms and provisions of the Act or of any rule, regulation, or order of the Commission.

(c) Except in cases of willfulness or those in which the public health, interest, or safety requires otherwise, no license or registration certificate shall be modified, suspended, or revoked unless, before the institution of proceedings therefor, facts or conduct that may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been given an opportunity to demonstrate or achieve compliance with all lawful requirements.

PART 31—GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

11. The authority citation for Part 31 continues to read as follows:

Authority: Secs. 81, 161, 183, 68 Stat. 935, 948, 954, as amended (42 U.S.C. 2111, 2201, 2233); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

§ 31.3 [Removed and Reserved]

12. Section 31.3 is removed and reserved.

13. In § 31.23, paragraph (b) is revised to read as follows:

§ 31.23 Criminal penalties.

* * * * *

(b) The regulations in part 31 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 31.1, 31.2, 31.4, 31.9, 31.22, and 31.23.

PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

14. The authority citation for Part 32 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

15. In § 32.1, paragraph (a) is revised to read as follows:

§ 32.1 Purpose and scope.

(a)(1) This part prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing byproduct material for sale or distribution to:

(i) Persons exempted from the licensing requirements of part 30 of this chapter, or equivalent regulations of an Agreement State; or

(ii) Persons generally licensed under part 31 of this chapter or equivalent regulations of an Agreement State; or

(iii) Persons licensed under part 35 of this chapter.

(2) This part prescribes requirements for the issuance of specific licenses to persons who introduce byproduct material into a product or material owned by or in the possession of a licensee or another, and regulations governing holders of such licenses.

(3) This part prescribes certain requirements governing holders of licenses to manufacture or distribute items containing byproduct material.

(4) This part describes procedures and prescribes requirements for the issuance of certificates of registration (covering radiation safety information about a product) to manufacturers or initial transferors of sealed sources or devices containing sealed sources.

* * * * *

16. In § 32.2, the definitions of *Committed dose* and *Sealed Source and Device Registry* are added in alphabetical order to read as follows:

§ 32.2 Definitions.

* * * * *

Committed dose means the radiation dose that will accumulate over time as a result of retention in the body of radioactive material. For the purposes of this part, committed dose is a generic term for internal dose and means committed effective dose equivalent, as defined in part 20 of this chapter, or committed effective dose as defined by the International Commission on Radiation Protection.

* * * * *

Sealed Source and Device Registry means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

17. In § 32.8, paragraph (b) is revised to read as follows:

§ 32.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 32.11, 32.12, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.21a, 32.22, 32.23, 32.25, 32.26, 32.27, 32.29, 32.30, 32.31, 32.32, 32.51, 32.51a, 32.52, 32.53, 32.54, 32.55, 32.56, 32.57, 32.58, 32.61, 32.62, 32.71, 32.72, 32.74, 32.201, 32.210, and 32.211.

* * * * *

18. In § 32.14, paragraphs (b)(4) and (b)(5) are revised to read as follows:

§ 32.14 Certain items containing byproduct material; requirements for license to apply or initially transfer.

* * * * *

(b) * * *

(4) Except for electron tubes and ionization chamber smoke detectors and timepieces containing promethium-147 or tritium in the form of gaseous tritium light sources, procedures for and results of prototype testing to demonstrate that the byproduct material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product;

(5) In the case of ionizing radiation measuring instruments and timepieces containing tritium in the form of paint, quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet;

* * * * *

19. In § 32.15, paragraph (c) is removed and reserved and paragraphs (a) and (b) are revised to read as follows:

§ 32.15 Same: Quality assurance, prohibition of transfer, and labeling.

(a) Each person licensed under § 32.14 for products for which quality control procedures are required must:

(1) Maintain quality assurance systems in the manufacture of the part or product, or the installation of the part into the product, in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed products are capable of performing their intended functions;

(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in the license issued under § 32.14, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded; and

(3) Visually inspect each unit in inspection lots. Any unit which has an observable physical defect that could adversely affect containment of the byproduct material shall be considered a defective unit.

(b) No person licensed under § 32.14 shall transfer to other persons for use under § 30.15 of this chapter or

equivalent regulations of an Agreement State:

(1) Any part or product tested and found defective under the criteria and procedures specified in the license issued under § 32.14, unless the defective part or product has been repaired or reworked, retested, and found by an independent inspector to meet the applicable acceptance criteria; or

(2) Any part or product contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (a)(2) of this section, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.14; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with the procedures specified in paragraphs (a)(2) and (b)(2)(i) of this section and any other criteria that may be required as a condition of the license issued under § 32.14.

(c) [Reserved]

* * * * *

20. In § 32.22, paragraph (a)(3) is added to read as follows:

§ 32.22 Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer.

(a) * * *

(3)(i) The Commission determines that the device meets the safety criteria in § 32.23; and

(ii) The device has been evaluated by NRC and registered in the Sealed Source and Device Registry.

* * * * *

21. In § 32.26, the introductory text is revised and paragraph (c) is added to read as follows:

§ 32.26 Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.

An application for a specific license to manufacture, process, or produce gas and aerosol detectors containing byproduct material and designed to protect health, safety, or property, or to initially transfer such products for use under § 30.20 of this chapter or equivalent regulations of an Agreement State, will be approved if:

* * * * *

(c)(1) The Commission determines that the device meets the safety criteria in § 32.27; and

(2) The device has been evaluated by NRC and registered in the Sealed Source and Device Registry.

22. Section 32.30 is added under Subpart A to read as follows:

§ 32.30 Certain industrial devices containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.

An application for a specific license to manufacture, process, produce, or initially transfer for sale or distribution devices containing byproduct material for use under § 30.22 of this chapter or equivalent regulations of an Agreement State will be approved if:

(a) The applicant satisfies the general requirements of § 30.33 of this chapter: However, the requirements of § 30.33(a)(2) and (a)(3) do not apply to an application for a license to transfer byproduct material in such industrial devices manufactured, processed, or produced under a license issued by an Agreement State;

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the industrial devices to demonstrate that the device will meet the safety criteria set forth in § 32.31. The information should include:

(1) A description of the device and its intended use or uses;

(2) The type and quantity of byproduct material in each unit;

(3) Chemical and physical form of the byproduct material in the device and changes in chemical and physical form that may occur during the useful life of the device;

(4) Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (b)(3) and (b)(12) of this section;

(5) Details of construction and design of the device as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the device;

(6) Maximum external radiation levels at 5 and 25 centimeters from any external surface of the device, averaged over an area not to exceed 10 square centimeters, and the method of measurement;

(7) Degree of access of human beings to the device during normal handling and use;

(8) Total quantity of byproduct material expected to be distributed in the devices annually;

(9) The expected useful life of the device;

(10) The proposed methods of labeling or marking the device and its point-of-sale package to satisfy the requirements of § 32.32(b);

(11) Procedures for prototype testing of the device to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the device;

(12) Results of the prototype testing of the device, including any change in the form of the byproduct material contained in the device, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features;

(13) The estimated external radiation doses and committed doses resulting from the intake of byproduct material in any one year relevant to the safety criteria in § 32.31 and the basis for these estimates;

(14) A determination that the probabilities with respect to the doses referred to in § 32.31(a)(4) meet the criteria of that paragraph;

(15) Quality control procedures to be followed in the fabrication of production lots of the devices and the quality control standards the devices will be required to meet; and

(16) Any additional information, including experimental studies and tests, required by the Commission.

(c)(1) The Commission determines that the device meets the safety criteria in § 32.31.

(2) The device is unlikely to be routinely used by members of the general public in a non-occupational environment.

(3) The device has been registered in the Sealed Source and Device Registry.

(4) The quantity of byproduct material in the device does not exceed 10^{-4} times the value listed in Appendix E to part 20 of this chapter as a Category 2 quantity.

23. Section 32.31 is added under Subpart A to read as follows:

§ 32.31 Certain industrial devices containing byproduct material: Safety criteria.

(a) An applicant for a license under § 32.30 shall demonstrate that the device is designed and will be manufactured so that:

(1) In normal use, handling, and storage of the quantities of exempt units likely to accumulate in one location, including during marketing, distribution, installation, and servicing of the device, it is unlikely that the external radiation dose in any one year, or the committed dose resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or

radioactive material from the device will exceed 200 μSv (20 mrem).

(2) It is unlikely that the external radiation dose in any one year, or the committed dose resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from disposal of the quantities of units likely to accumulate in the same disposal site will exceed 10 μSv (1 mrem).

(3) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the device from wear and abuse likely to occur in normal handling and use of the device during its useful life.

(4) In use, handling, storage, and disposal of the quantities of exempt units likely to accumulate in one location, including during marketing, distribution, installation, and servicing of the device, the probability is low that the containment, shielding, or other safety features of the device would fail under such circumstances that a person would receive an external radiation dose or committed dose in excess of 5 mSv (500 mrem), and the probability is negligible that a person would receive an external radiation dose or committed dose of 100 mSv (10 rem) or greater.[1]

(b) An applicant for a license under § 32.30 shall demonstrate that, even in unlikely scenarios of misuse, including those resulting in direct exposure to the unshielded source removed from the device for 1,000 hours at an average distance of 1 meter and those resulting in dispersal and subsequent intake of 10^{-4} of the quantity of byproduct material (or in the case of tritium, an intake of 10 percent), a person will not receive an external radiation dose or committed dose in excess of 100 mSv (10 rem), and, if the unshielded source is small enough to fit in a pocket, that the dose to localized areas of skin averaged over areas no larger than 1 square centimeter from carrying the unshielded source in a pocket for 80 hours will not exceed 2 Sv (200 rem).

24. Section 32.32 is added under Subpart A to read as follows:

§ 32.32 Conditions of licenses issued under § 32.30: Quality control, labeling, and reports of transfer.

Each person licensed under § 32.30 shall:

(a) Carry out adequate control procedures in the manufacture of the device to ensure that each production lot meets the quality control standards approved by the Commission;

(b) Label or mark each device and its point-of-sale package so that:

(1) Each item has a durable, legible, readily visible label or marking on the external surface of the device containing:

(i) The following statement: "CONTAINS RADIOACTIVE MATERIAL";

(ii) The name of the radionuclide(s) and quantity(ies) of activity;

(iii) An identification of the person licensed under § 32.30 to transfer the device for use under § 30.22 of this chapter or equivalent regulations of an Agreement State; and

(iv) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information).

(2) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(i) The name of the radionuclide and quantity of activity;

(ii) An identification of the person licensed under § 32.30 to transfer the device for use under § 30.22 of this chapter or equivalent regulations of an Agreement State; and

(iii) The following or a substantially similar statement: "THIS DEVICE CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NUCLEAR REGULATORY COMMISSION SAFETY CRITERIA IN 10 CFR 32.31. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS."

(3) Each device and point-of-sale package contains such other information as may be required by the Commission; and

(c) Maintain records of all transfers and file a report with the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the devices are transferred for use under § 30.22 of this chapter or equivalent regulations of an Agreement State.

(3) The report must include the following information on devices transferred to other persons for use under § 30.22 or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each device and the model number(s);

(ii) For each radionuclide in each type of device and each model number, the total quantity of the radionuclide; and

(iii) The number of units of each type of device transferred during the reporting period by model number.

(4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year.

(ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.30 shall file a report for the current calendar year within 30 days after ceasing distribution.

(5) If no transfers of byproduct material have been made under § 32.30 during the reporting period, the report must so indicate.

(6) The licensee shall maintain the record of a transfer for a period of one year after the transfer is included in a report to the Commission.

25. In § 32.51, paragraph(a)(6) is added to read as follows:

§ 32.51 Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture, or initially transfer.

(a) * * *

(6) The device has been registered in the Sealed Source and Device Registry.

* * * * *

26. In § 32.53, paragraphs (b)(5) and (d)(4) are revised and paragraphs (e) and (f) are added to read as follows:

§ 32.53 Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer.

* * * * *

(b) * * *

(5) Quality assurance procedures to be followed that are sufficient to ensure compliance with § 32.55;

* * * * *

(d) * * *

(4) Prototypes of the device have been subjected to and have satisfactorily passed the tests required by paragraph (e) of this section.

(e) The applicant must subject at least five prototypes of the device to tests as follows:

(1) The devices are subjected to tests that adequately take into account the

[1] It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The following values may be used as guides in estimating compliance with the criteria: Low—not more than one such failure/incident per year for each 10,000 exempt units distributed. Negligible—not more than one such failure/incident per year for each one million exempt units distributed.

individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

(2) The devices are inspected for evidence of physical damage and for loss of tritium or promethium-147, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (e)(3) of this section.

(3) Device designs are rejected for which the following has been detected for any unit:

(i) A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device; or

(ii) Surface contamination of tritium or promethium-147 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(iii) Any other evidence of physical damage.

(f) The device has been registered in the Sealed Source and Device Registry.

27. Section 32.55 is revised to read as follows:

§ 32.55 Same: Quality assurance, prohibition of transfer.

(a) Each person licensed under § 32.53 must visually inspect each device and must reject any that has an observable physical defect that could adversely affect containment of the tritium or promethium-147.

(b) Each person licensed under § 32.53 must:

(1) Maintain quality assurance systems in the manufacture of the luminous safety device in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in paragraph (c) of this section and in the license issued under § 32.53, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

(c) The licensee must subject each inspection lot to:

(1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion.

(2) Inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing, using methods of inspection adequate for applying the following criteria for defective:

(i) A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device;

(ii) Levels of radiation in excess of 5 microgray (0.5 millirad) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, if the device contains promethium-147; and

(iii) Any other criteria specified in the license issued under § 32.53.

(d) No person licensed under § 32.53 shall transfer to persons generally licensed under § 31.7 of this chapter, or under an equivalent general license of an Agreement State:

(1) Any luminous safety device tested and found defective under any condition of a license issued under § 32.53, or paragraph (b) of this section, unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(2) Any luminous safety device contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (b)(2) of this section, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.53; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (b)(2) and (d)(2)(i) of this section and any other criteria that may be required as a condition of the license issued under § 32.53.

28. Section 32.56 is revised to read as follows:

§ 32.56 Same: Material transfer reports.

(a) Each person licensed under § 32.53 shall file an annual report with the Director, Office of Federal and State Materials and Environmental Management Programs, ATTN: Document Control Desk/GLTS, by an appropriate method listed in § 30.6(a) of this chapter, which must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under § 31.7 of this chapter. The report must identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report must cover the year ending June 30 and must be filed within thirty (30) days thereafter. If no transfers have been made to or from persons generally licensed under § 31.7 of this chapter during the reporting period, the report must so indicate.

(b) Each person licensed under § 32.53 shall report annually all transfers of devices to persons for use under a general license in an Agreement State's regulations that are equivalent to § 31.7 of this chapter to the responsible Agreement State agency. The report must state the total quantity of tritium or promethium-147 transferred, identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. If no transfers have been made to a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of the agency.

29. In § 32.57, paragraph (d)(2) is revised and paragraph (e) is added to read as follows:

§ 32.57 Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer.

* * * * *

(d) * * *

(2) The source has been subjected to and has satisfactorily passed appropriate tests required by paragraph (e) of this section.

(e) The applicant must subject at least five prototypes of each source that is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 to tests as follows:

(1) The initial quantity of radioactive material deposited on each source is measured by direct counting of the source.

(2) The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion.

(3) The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (e)(4) of this section.

(4) Source designs are rejected for which the following has been detected for any unit: removal of more than 0.185

kilobecquerel (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.

30. Section 32.59 is revised to read as follows:

§ 32.59 Same: Leak testing of each source.

Each person licensed under § 32.57 must perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under § 31.8 of this chapter or under equivalent regulations of an Agreement State. This test must be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper must be measured using methods capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 by the methods described in this section, the source must be rejected and must not be transferred to a general licensee under § 31.8 of this chapter, or equivalent regulations of an Agreement State.

31. In § 32.61, paragraph (e)(4) is revised and paragraphs (f) and (g) are added to read as follows:

§ 32.61 Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer.

* * * * *

(e) * * *

(4) Prototypes of the device have been subjected to and have satisfactorily passed the tests required by paragraph (f) of this section.

* * * * *

(f) The applicant must subject at least five prototypes of the device to tests as follows:

(1) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

(2) The devices are inspected for evidence of physical damage and for loss of strontium-90 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (f)(3) of this section.

(3) Device designs are rejected for which the following has been detected for any unit:

(i) A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device; or

(ii) Surface contamination of strontium-90 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(iii) Any other evidence of physical damage.

(g) The device has been registered in the Sealed Source and Device Registry.

32. In § 32.62, paragraphs (c), (d), and (e) are revised to read as follows:

§ 32.62 Same: Quality assurance; prohibition of transfer.

* * * * *

(c) Each person licensed under § 32.61 must:

(1) Maintain quality assurance systems in the manufacture of the ice detection device containing strontium-90 in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in paragraph (d) of this section and in the license issued under § 32.61, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

(d) Each person licensed under § 32.61 must subject each inspection lot to:

(1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could possibly affect the effective containment of strontium-90, such as absolute pressure and water immersion.

(2) Inspection for evidence of physical damage, containment failure, or for loss of strontium-90 after each stage of testing, using methods of inspection adequate to determine compliance with the following criteria for defective: a leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device and any other criteria specified in the license issued under § 32.61.

(e) No person licensed under § 32.61 shall transfer to persons generally licensed under § 31.10 of this chapter, or under an equivalent general license of an Agreement State:

(1) Any ice detection device containing strontium-90 tested and found defective under the criteria specified in a license issued under § 32.61, unless the defective ice detection device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(2) Any ice detection device containing strontium-90 contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (c)(2) of this section, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.61; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (c)(2) and (e)(2)(i) of this section and any other criteria as may be required as a condition of the license issued under § 32.61.

Subpart C—Specifically Licensed Items

33. The heading of Subpart C is revised to read as previously set out.

34. Sections 32.72 and 32.74 are transferred from Subpart B to Subpart C; § 32.74 is amended by adding paragraph (a)(4) to read as follows:

§ 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.

(a) * * *

(4) The source or device has been registered in the Sealed Source and Device Registry.

* * * * *

§ 32.101 [Removed]

35. Section 32.101 is removed.

§ 32.102 [Removed]

36. Section 32.102 is removed.

§ 32.103 [Removed]

37. Section 32.103 is removed.

§ 32.110 [Removed]

38. Section 32.110 is removed.

Subpart D—Sealed Source and Device Registration

39. The heading of Subpart D is revised to read as previously set out.

§ 32.201 [Amended]

40. Section 32.201 is transferred from Subpart D to Subpart C.

41. In § 32.210, paragraphs (a), (b), (d), and (e) are revised, and paragraphs (g) and (h) are added to read as follows:

§ 32.210 Registration of product information.

(a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit

a request to the NRC for evaluation of radiation safety information about its product and for its registration.

(b) The request for review must be sent to the NRC's Office of Federal and State Materials and Environmental Management Programs, ATTN: SSDR by an appropriate method listed in § 30.6(a) of this chapter.

* * * * *

(d) The NRC normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor. The NRC shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property. Subpart A of this part includes specific criteria that apply to certain exempt products and Subpart B includes specific criteria applicable to certain generally licensed devices. Subpart C includes specific provisions that apply to certain specifically licensed items.

(e) After completion of the evaluation, the Commission issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.

* * * * *

(g) Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

(1) Calibration and reference sources containing no more than:

(i) 37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or

(ii) 0.37 MBq (10 μCi), for alpha emitting radionuclides; or

(2) The intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and

(i) The intended recipients are licensed under part 33 of this chapter or comparable Agreement State provisions; or

(ii) The recipients are authorized for research and development; or

(iii) The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide.

(h) After the certificate is issued, the Commission may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the Commission will complete its evaluation in accordance with criteria specified in this section. The Commission may request such additional information as it considers necessary to conduct its review.

42. Section 32.211 is added under Subpart D to read as follows:

§ 32.211 Inactivation of certificates of registration of sealed sources and devices.

A specific licensee who no longer intends to manufacture or initially transfer a sealed source or device registered with the Commission shall request inactivation of the registration certificate. Such a request shall be made no later than two years after the last initial transfer of a source or device covered by the certificate. If this cessation of activity is associated with the termination of a specific license, the request for inactivation of registration should state the intent to terminate a license giving the specific license number. A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

43. In § 32.303, paragraph (b) is revised to read as follows:

§ 32.303 Criminal penalties.

* * * * *

(b) The regulations in part 32 that are not issued under subsections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 32.1, 32.2, 32.8, 32.11, 32.14, 32.18, 32.21, 32.22, 32.23, 32.24, 32.26, 32.27, 32.28, 32.30, 32.31, 32.51, 32.53, 32.57, 32.61, 32.71, 32.72, 32.74, 32.301, and 32.303.

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

44. The authority citation for part 40 continues to read as follows:

Authority: Secs. 62, 63, 64, 65, 81, 161, 182, 183, 186, 68 Stat. 932, 933, 935, 948, 953, 954, 955, as amended, secs. 11e(2), 83, 84, Pub. L. 95–604, 92 Stat. 3033, as amended, 3039, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2232, 2233, 2236, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688 (42 U.S.C. 2021); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 275, 92 Stat. 3021, as amended by Pub. L. 97–415, 96 Stat. 2067 (42 U.S.C. 2022); sec. 193, 104 Stat. 2835, as amended by Pub. L. 104–134, 110 Stat. 1321, 1321–349 (42 U.S.C. 2243); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note). Section 40.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 40.31(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 40.46 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 40.71 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

45. In § 40.5, paragraph (b)(1)(iv) is revised to read as follows:

§ 40.5 Communications.

* * * * *

(b) * * *

(1) * * *

(iv) Distribution of products containing radioactive material to persons exempt under §§ 32.11 through 32.30 of this chapter.

* * * * *

PART 70—DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

46. The authority citation for part 70 continues to read as follows:

Authority: Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, 948, 953, 954, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2282, 2297f); secs. 201, as amended, 202, 204, 206, 88 Stat. 1242, as amended, 1244, 1245, 1246 (42 U.S.C. 5841, 5842, 5845, 5846). Sec. 193, 104 Stat. 2835, as amended by Pub. L. 104–134, 110 Stat. 1321, 1321–349 (42 U.S.C. 2243); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Sections 70.1(c) and 70.20a(b) also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 70.7 is also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Section 70.21(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 70.31 also issued under sec. 57d, Pub. L. 93–377, 88 Stat. 475 (42 U.S.C. 2077). Sections 70.36 and 70.44 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 70.81 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237). Section 70.82 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

47. In § 70.5, paragraph (b)(1)(iv) is revised to read as follows:

§ 70.5 Communications.

* * * * *

(b) * * *

(1) * * *

(iv) Distribution of products containing radioactive material to persons exempt under §§ 32.11 through 32.30 of this chapter.

* * * * *

Dated at Rockville, Maryland, this 17th day of June 2010.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2010–15202 Filed 6–23–10; 8:45 am]

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Federal Register

Thursday,
June 24, 2010

Part IV

Department of Education

National Institute on Disability and Rehabilitation Research (NIDRR)—Disability and Rehabilitation Research Projects and Centers Program—Rehabilitation Research and Training Centers (RRTCs)—Improved Outcomes for Individuals With Serious Mental Illness and Co-Occurring Conditions; Office of Special Education and Rehabilitative Services; Notices

DEPARTMENT OF EDUCATION

National Institute on Disability and Rehabilitation Research (NIDRR)—Disability and Rehabilitation Research Projects and Centers Program—Rehabilitation Research and Training Centers (RRTCs)—Improved Outcomes for Individuals With Serious Mental Illness and Co-Occurring Conditions

Catalog of Federal Domestic Assistance (CFDA) Number: 84.133B–5.

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice of final priority.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services announces a priority for the Disability and Rehabilitation Research Projects and Centers Program administered by NIDRR. Specifically, this notice announces a priority for an RRTC on Improved Outcomes for Individuals With Serious Mental Illness and Co-Occurring Conditions. The Assistant Secretary may use this priority for competitions in fiscal year (FY) 2010 and later years. We take this action to focus research attention on areas of national need. We intend this priority to improve rehabilitation services and outcomes for individuals with disabilities.

DATES: *Effective Date:* This priority is effective July 26, 2010.

FOR FURTHER INFORMATION CONTACT: Lynn Medley, U.S. Department of Education, 400 Maryland Avenue, SW., Room 5140, Potomac Center Plaza (PCP), Washington, DC 20202. Telephone: (202) 245–7338 or by e-mail: *Lynn.Medley@ed.gov*.

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: This notice of final priority is in concert with NIDRR's Final Long-Range Plan for FY 2005–2009 (Plan). The Plan, which was published in the **Federal Register** on February 15, 2006 (71 FR 8165), can be accessed on the Internet at the following site: *http://www.ed.gov/about/offices/list/osers/nidrr/policy.html*.

Through the implementation of the Plan, NIDRR seeks to: (1) Improve the quality and utility of disability and rehabilitation research; (2) foster an exchange of expertise, information, and training to facilitate the advancement of knowledge and understanding of the unique needs of traditionally underserved populations; (3) determine best strategies and programs to improve rehabilitation outcomes for underserved populations; (4) identify research gaps; (5) identify mechanisms of integrating research and practice; and (6) disseminate findings.

Purpose of Program: The purpose of the Disability and Rehabilitation Research Projects and Centers Program is to plan and conduct research, demonstration projects, training, and related activities, including international activities, to develop methods, procedures, and rehabilitation technology, that maximize the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities, especially individuals with the most severe disabilities, and to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended.

RRTC Program

The purpose of the RRTC program is to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended, through advanced research, training, technical assistance, and dissemination activities in general problem areas, as specified by NIDRR. Such activities are designed to benefit rehabilitation service providers, individuals with disabilities, and the family members or other authorized representatives of individuals with disabilities. In addition, NIDRR intends to require all RRTC applicants to meet the requirements of the *General Rehabilitation Research and Training Centers (RRTC) Requirements* priority that it published in a notice of final priorities in the **Federal Register** on February 1, 2008 (73 FR 6132). Additional information on the RRTC program can be found at: *http://www.ed.gov/rschstat/research/pubs/res-program.html#RRTC*.

Statutory and Regulatory Requirements of RRTCs

RRTCs must—

- Carry out coordinated advanced programs of rehabilitation research;
- Provide training, including graduate, pre-service, and in-service training, to help rehabilitation personnel more effectively provide rehabilitation services to individuals with disabilities;
- Provide technical assistance to individuals with disabilities, their representatives, providers, and other interested parties;
- Disseminate informational materials to individuals with disabilities, their representatives, providers, and other interested parties; and
- Serve as centers of national excellence in rehabilitation research for individuals with disabilities, their representatives, providers, and other interested parties.

Applicants for RRTC grants must also demonstrate in their applications how they will address, in whole or in part, the needs of individuals with disabilities from minority backgrounds.

Program Authority: 29 U.S.C. 762(g) and 764(b)(2).

Applicable Program Regulations: 34 CFR part 350.

We published a notice of proposed priority (NPP) for NIDRR's Disability and Rehabilitation Research Projects and Centers Program in the **Federal Register** on April 23, 2010 (75 FR 21282). The NPP included a background statement that described our rationale for the priority proposed in that notice.

There are no differences between the proposed priority and this final priority.

Public Comment: In response to our invitation in the NPP, we did not receive any substantive comments on the proposed priority.

Final Priority

The Assistant Secretary for Special Education and Rehabilitative Services announces a priority for a Rehabilitation Research and Training Center (RRTC) on Improved Outcomes for Individuals with Serious Mental Illness and Co-Occurring Conditions. The RRTC must conduct research to adapt, modify, and enhance health and mental health models to improve health and employment outcomes for individuals with serious mental illness (SMI) and co-occurring conditions. The RRTC must conduct research, knowledge translation, training, dissemination, and technical assistance within a framework of self-management and consumer-directed services. Under this priority, the RRTC must contribute to the following outcomes:

(a) Increased knowledge that can be used to enhance the health and well-being of individuals with SMI and co-occurring conditions. The RRTC must contribute to this outcome by:

(1) Conducting research to develop a better understanding of the health, and health care needs of individuals with SMI and co-occurring conditions.

(2) Conducting research to identify or develop and then test interventions that aim to improve health outcomes and promote recovery among individuals living with SMI and co-occurring conditions. These interventions must include individual-level health promotion strategies, such as peer supports and consumer control, as well as system-level strategies for the

delivery of physical and mental health services. These interventions must be based on the findings of research conducted under paragraph (a)(1) of this priority. In carrying out this activity, the grantee must investigate the applicability of strategies that have proven successful with the general population or other subpopulations to determine if they are effective with individuals with SMI and co-occurring conditions.

(b) Improved employment outcomes among individuals with SMI and co-occurring conditions. The RRTC must contribute to this outcome by conducting research that demonstrates how improvements in health service delivery mechanisms, self-management, peer support, and consumer control affect employment outcomes in individuals with SMI and co-occurring conditions. In carrying out this activity the grantee must utilize one or more of the interventions developed under paragraph (a)(2) of this priority.

(c) Increased incorporation of research findings related to SMI, co-occurring conditions, health management, and employment into practice or policy. The RRTC must contribute to this outcome by coordinating with appropriate NIDRR-funded knowledge translation grantees to advance their work in the following areas:

(1) Developing, evaluating, or implementing strategies to increase utilization of research findings related to SMI, co-occurring conditions, health management, and employment.

(2) Conducting training, technical assistance, and dissemination activities to increase utilization of research findings related to SMI, co-occurring conditions, health management, and employment.

Types of Priorities

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register.** The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) Awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does *not* solicit applications. In any year in which we choose to use this priority, we invite applications through a notice in the **Federal Register.**

Executive Order 12866: This notice has been reviewed in accordance with Executive Order 12866. Under the terms of the order, we have assessed the potential costs and benefits of this final regulatory action.

The potential costs associated with this final regulatory action are those resulting from statutory requirements and those we have determined as necessary for administering this program effectively and efficiently.

In assessing the potential costs and benefits—both quantitative and qualitative—of this final regulatory action, we have determined that the benefits of the final priority justify the costs.

Discussion of Costs and Benefits

The benefits of the Disability and Rehabilitation Research Projects and Centers Program have been well established over the years in that similar projects have been completed successfully. This final priority will generate new knowledge through research and development.

Another benefit of this final priority is that the establishment of a new RRTC will advance research to improve the lives of individuals with disabilities. The new RRTC will disseminate and promote the use of new information that will improve the options for individuals with disabilities to obtain, retain, and advance in employment.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or computer diskette) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue, SW., room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: You can view this document, as well as all other documents of this Department published in the **Federal Register,** in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.* To use PDF you must have Adobe Acrobat Reader, which is available free at this site.

Note: The official version of this document is the document published in the **Federal Register.** Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: June 21, 2010.

Alexa Posny,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2010–15344 Filed 6–23–10; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Office of Special Education and Rehabilitative Services; Overview Information; National Institute on Disability and Rehabilitation Research (NIDRR)—Disability and Rehabilitation Research Projects and Centers Program—Rehabilitation Research and Training Centers (RRTCs)—Improved Outcomes for Individuals With Serious Mental Illness and Co-Occurring Conditions; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2010

Catalog of Federal Domestic Assistance (CFDA) Number: 84.133B–5.

Dates:

Applications Available: June 24, 2010.

Date of Pre-Application Meeting: July 8, 2010.

Deadline for Transmittal of Applications: August 23, 2010.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the RRTC program is to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended, through advanced research, training, technical assistance, and dissemination activities in general problem areas, as specified by NIDRR. Such activities are designed to benefit rehabilitation service providers, individuals with disabilities, and the family members or other authorized representatives of individuals with disabilities.

Additional information on the RRTC program can be found at: *http://www.ed.gov/rschstat/research/pubs/res-program.html#RRTC.*

Priorities: NIDRR has established two absolute priorities for this competition.

Absolute Priorities: The *General Rehabilitation Research and Training Centers (RRTC) Requirements* priority is from the notice of final priorities for the Disability and Rehabilitation Research Projects and Centers program, published in the **Federal Register** on February 1, 2008 (73 FR 6132). The *Improved Outcomes for Individuals with Serious Mental Illness and Co-Occurring Conditions* priority is from the notice of final priority for the Disability and Rehabilitation Research Projects and Centers Program, published elsewhere in this issue of the **Federal Register.**

For FY 2010, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3) we consider only applications that meet these priorities.

These priorities are:

General Rehabilitation Research and Training Centers (RRTC) Requirements and *Improved Outcomes for Individuals with Serious Mental Illness and Co-Occurring Conditions.*

Note: The full text of each of these priorities is included in the applicable notice of final priorities published in the **Federal Register** and in the applicable application package.

Program Authority: 29 U.S.C. 762(g) and 764(b)(2).

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 80, 81, 82, 84, 85, 86, and 97. (b) The regulations for this program in 34 CFR part 350. (c) The notice of final priorities for the Disability and Rehabilitation Research Projects and Centers program, published in the **Federal Register** on February 1, 2008 (73 FR 6132). (d) The notice of final priority for the Disability and Rehabilitation Research Projects and Centers program, published elsewhere in this issue of the **Federal Register**.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $950,000.

Maximum Award: We will reject any application that proposes a budget exceeding $950,000 for a single budget period of 12 months. The Assistant Secretary for Special Education and Rehabilitative Services may change the maximum amount through a notice published in the **Federal Register**.

Note: The maximum amount includes direct and indirect costs. A grantee may not collect more than 15 percent of the total grant award as indirect cost charges (34 CFR 350.23).

Estimated Number of Awards: 1.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* States; public or private agencies, including for-profit agencies; public or private organizations, including for-profit organizations; IHEs; and Indian Tribes and Tribal organizations.

2. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

IV. Application and Submission Information

1. *Address to Request Application Package:* ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a telecommunications device for the deaf (TDD), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *http://www.EDPubs.gov* or at its e-mail address: *edpubs@inet.ed.gov*.

If you request an application package from ED Pubs, be sure to identify this program or competition as follows: CFDA number 84.133B–5.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or computer diskette) by contacting the person or team listed under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you limit Part III to the equivalent of no more than 125 pages, using the following standards:

- A "page" is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative. Single spacing may be used for titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The recommended page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative section (Part III).

The application package will provide instructions for completing all components to be included in the application. Each application must include a cover sheet (Standard Form 424); budget requirements (ED Form 524) and narrative justification; other required forms; an abstract; Human Subjects narrative; Part III narrative; resumes of staff; and other related materials, if applicable.

3. *Submission Dates and Times:*

Applications Available: June 24, 2010.

Date of Pre-Application Meeting: Interested parties are invited to participate in a pre-application meeting and to receive information and technical assistance through individual consultation with NIDRR staff. The pre-application meeting will be held on July 8, 2010. Interested parties may participate in this meeting by conference call with NIDRR staff from the Office of Special Education and Rehabilitative Services between 1:00 p.m. and 3:00 p.m., Washington, DC time. NIDRR staff also will be available from 3:30 p.m. to 4:30 p.m., Washington, DC time, on the same day, by telephone, to provide information and technical assistance through individual consultation. For further information or to make arrangements to participate in the meeting via conference call or for an individual consultation, contact Lynn Medley, U.S. Department of Education, Potomac Center Plaza (PCP), room 5140, 550 12th Street, SW., Washington, DC 20202. Telephone: (202) 245–7338 or by e-mail: *Lynn.Medley@ed.gov*.

Deadline for Transmittal of Applications: August 23, 2010.

Applications for grants under this competition must be submitted electronically using the Electronic Grant Application System (e-Application) accessible through the Department's e-Grants site. For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the

electronic submission requirement, please refer to section IV. 7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under *For Further Information Contact* in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

4. *Intergovernmental Review:* This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and Central Contractor Registry:* To do business with the Department of Education, (1) you must have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN); (2) you must register both of those numbers with the Central Contractor Registry (CCR), the Government's primary registrant database; and (3) you must provide those same numbers on your application.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one business day.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2–5 weeks for your TIN to become active.

The CCR registration process may take five or more business days to complete. If you are currently registered with the CCR, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your CCR registration on an annual basis. This may take three or more business days to complete.

7. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. Electronic Submission of Applications

Applications for grants under the Rehabilitation Research and Training Centers (RRTCs)—Improved Outcomes for Individuals with Serious Mental Illness and Co-Occurring Conditions competition—CFDA Number 84.133B–5 must be submitted electronically using e-Application, accessible through the Department's e-Grants Web site at: *http://e-grants.ed.gov.*

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

While completing your electronic application, you will be entering data online that will be saved into a database. You may not e-mail an electronic copy of a grant application to us.

Please note the following:

- You must complete the electronic submission of your grant application by 4:30:00 p.m., Washington, DC time, on the application deadline date. E-Application will not accept an application for this competition after 4:30:00 p.m., Washington, DC time, on the application deadline date. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the application process.
- The hours of operation of the e-Grants Web site are 6:00 a.m. Monday until 7:00 p.m. Wednesday; and 6:00 a.m. Thursday until 8:00 p.m. Sunday, Washington, DC time. Please note that, because of maintenance, the system is unavailable between 8:00 p.m. on Sundays and 6:00 a.m. on Mondays, and between 7:00 p.m. on Wednesdays and 6:00 a.m. on Thursdays, Washington, DC time. Any modifications to these hours are posted on the e-Grants Web site.
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: the Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications. You must attach any narrative sections of your application as files in a .DOC (document), .RTF (rich text), or .PDF (Portable Document) format. If you upload a file type other than the three file types specified in this paragraph or submit a password protected file, we will not review that material.
- Your electronic application must comply with any page limit requirements described in this notice.
- Prior to submitting your electronic application, you may wish to print a copy of it for your records.
- After you electronically submit your application, you will receive an automatic acknowledgment that will include a PR/Award number (an identifying number unique to your application).
- Within three working days after submitting your electronic application, fax a signed copy of the SF 424 to the Application Control Center after following these steps:

(1) Print SF 424 from e-Application.

(2) The applicant's Authorizing Representative must sign this form.

(3) Place the PR/Award number in the upper right hand corner of the hard-copy signature page of the SF 424.

(4) Fax the signed SF 424 to the Application Control Center at (202) 245–6272.

- We may request that you provide us original signatures on other forms at a later date.

Application Deadline Date Extension in Case of e-Application Unavailability: If you are prevented from electronically submitting your application on the application deadline date because e-Application is unavailable, we will grant you an extension of one business day to enable you to transmit your application electronically, by mail, or by hand delivery. We will grant this extension if—

(1) You are a registered user of e-Application and you have initiated an electronic application for this competition; and

(2)(a) E-Application is unavailable for 60 minutes or more between the hours of 8:30 a.m. and 3:30 p.m., Washington, DC time, on the application deadline date; or

(b) E-Application is unavailable for any period of time between 3:30 p.m. and 4:30:00 p.m., Washington, DC time, on the application deadline date.

We must acknowledge and confirm these periods of unavailability before granting you an extension. To request this extension or to confirm our acknowledgment of any system unavailability, you may contact either (1) the person listed elsewhere in this notice under *For Further Information Contact* (*see* VII. Agency Contact) or (2) the e-Grants help desk at 1–888–336–8930. If e-Application is unavailable due to technical problems with the system and, therefore, the application deadline is extended, an e-mail will be sent to all registered users who have initiated an e-Application. Extensions referred to in this section apply only to the unavailability of e-Application.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through e-Application because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to e-Application; *and*
- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application. If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Lynn Medley, U.S. Department of Education, 400 Maryland Avenue, SW., Room 5140, PCP, Washington, DC 20202–2700. FAX: (202) 245–7323.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. Submission of Paper Applications by Mail

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.133B–5), LBJ Basement Level 1, 400 Maryland Avenue, SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. Submission of Paper Applications by Hand Delivery

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application, by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.133B–5), 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260. The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this grant notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

Selection Criteria: The selection criteria for this competition are from 34 CFR 350.54 and are listed in the application package.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *http://www.ed.gov/fund/grant/apply/appforms/appforms.html.*

Note: NIDRR will provide information by letter to grantees on how and when to submit the final performance report.

4. *Performance Measures:* To evaluate the overall success of its research program, NIDRR assesses the quality of its funded projects through a review of grantee performance and products. Each year, NIDRR examines a portion of its grantees to determine:

- The percentage of NIDRR-supported fellows, post-doctoral trainees, and doctoral students who publish results of NIDRR-sponsored research in refereed journals.

- The number of accomplishments (*e.g.,* new or improved tools, methods, discoveries, standards, interventions, programs, or devices) developed or tested with NIDRR funding that have been judged by expert panels to be of high quality and to advance the field.
- The average number of publications per award based on NIDRR-funded research and development activities in refereed journals.
- The percentage of new NIDRR grants that assess the effectiveness of interventions, programs, and devices using rigorous methods.

Each grantee must annually report on its performance through NIDRR's Annual Performance Report (APR) form. NIDRR uses APR information submitted by grantees to assess progress on these measures.

VII. Agency Contact

For Further Information Contact: Lynn Medley, U.S. Department of Education, 400 Maryland Avenue, SW., Room 5140, PCP, Washington, DC 20202–2700. Telephone: (202) 245–7338 or by e-mail: *Lynn.Medley@ed.gov.*

If you use a TDD, call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or computer diskette) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue, SW., Room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.* To use PDF you must have Adobe Acrobat Reader, which is available free at this site.

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Dated: June 21, 2010.

Alexa Posny,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2010–15345 Filed 6–23–10; 8:45 am]

BILLING CODE 4000–01–P

Federal Register

Thursday,
June 24, 2010

Part V

Department of Health and Human Services

Department of Transportation

Notice of Funding Availability for the Department of Housing and Urban Development's Community Challenge Planning Grants and the Department of Transportation's TIGER II Planning Grants; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

DEPARTMENT OF TRANSPORTATION

[Docket No. FR–5415–N–12]

Notice of Funding Availability for the Department of Housing and Urban Development's Community Challenge Planning Grants and the Department of Transportation's TIGER II Planning Grants

AGENCY: Office of Sustainable Housing and Communities, Office of the Deputy Secretary, HUD; and Office of the Secretary, DOT.

ACTION: Notice of Funding Availability (NOFA).

SUMMARY: This notice announces the availability of funding and requests proposals for the Department of Housing and Urban Development's ("HUD's") Community Challenge Planning Grants ("Community Challenge Planning Grants") in conjunction with a portion of the Department of Transportation's ("DOT's") National Infrastructure Investments Grants that can be used for transportation planning grants.

On December 16, 2009, the President signed the Consolidated Appropriations Act, 2010 (Pub. L. 111–117) that provided $40 million for HUD's Community Challenge Planning Grants and up to $35 million for DOT's transportation planning grants to be awarded as part of the National Infrastructure Investments program. The National Infrastructure Investments program is similar, but not identical to, the Transportation Investment Generating Economic Recovery, or "TIGER Discretionary Grant Program." Because of the similarity in program structure, DOT is referring to the grants for National Infrastructure Investments under the FY 2010 Appropriations Act as "TIGER II Discretionary Grants" and the transportation planning grants as "TIGER II Planning Grants."

HUD's $40 million Community Challenge Planning Grant Program will foster reform and reduce barriers to achieving affordable, economically vital, and sustainable communities. Such efforts may include amending or replacing local master plans, zoning codes, and building codes, either on a jurisdiction-wide basis or in a specific neighborhood, district, corridor, or sector to promote mixed-use development, affordable housing, the reuse of older buildings and structures for new purposes, and similar activities with the goal of promoting sustainability at the local or neighborhood level. HUD's Community Challenge Planning Grant Program also supports the development of affordable housing through the development and adoption of inclusionary zoning ordinances and other activities such as acquisition of land for affordable housing projects.

The Community Challenge Planning Grant Program differs from HUD's Sustainable Communities Regional Planning Grant Program, a $100 million program also created in the FY2010 Appropriations Act. While the latter program is designed to support regional planning efforts, the Community Challenge Planning Grant Program focuses on individual jurisdictions and more localized planning. HUD will publish a separate NOFA for the Sustainable Communities Regional Planning Grant Program.

DOT is authorized to use up to $35 million of the funds available for TIGER II Discretionary Grants for TIGER II Planning Grants to fund the planning, preparation, or design of surface transportation projects that would be eligible for funding under the TIGER II Discretionary Grant program.

DOT and HUD have decided to issue this NOFA jointly in order to better align transportation, housing, economic development, and land use planning and to improve linkages between DOT and HUD's programs. HUD's funding is designed to target housing, economic development, and land use planning strategies that will increase the efficiency and effectiveness of a related transportation project being planned. Therefore, DOT and HUD believe this joint effort has the potential to encourage and reward more holistic planning efforts that result in better projects being built with Federal dollars. The effort is also consistent with the Obama Administration's priority on removing artificial barriers between Federal programs and barriers to State and local governmental level innovation.

On April 26, 2010 (75 FR 21695), DOT published an interim notice announcing the availability of funding for TIGER II Discretionary Grants. Because the TIGER II Discretionary Grant program is a new program, the interim notice requested comments on the proposed selection criteria and guidance for awarding TIGER II Discretionary Grants. In the interim notice, DOT specifically requested comments on its intention to conduct a multi-agency evaluation and award process with HUD for the Community Challenge Planning Grants and the TIGER II Planning Grants. DOT indicated that this multi-agency approach for the planning grants would be consistent with DOT and HUD's participation in the "Partnership for Sustainable Communities" with the U.S. Environmental Protection Agency ("EPA") to help American families in all communities—rural, suburban and urban—gain better access to affordable housing, more transportation options, lower transportation costs, and a cleaner environment. HUD and DOT have considered the comments that were submitted in accordance with the interim notice and decided to conduct a multi-agency evaluation and award process. The details of this multi-agency planning grant program, including information about eligibility, selection criteria, and pre-application and application requirements are included in this joint notice. The final notice for the TIGER II Discretionary Grant program (the "TIGER II Discretionary Grant NOFA") was published on June 1, 2010 (75 FR 30460). Interested parties are encouraged to review the TIGER II Discretionary Grant NOFA for more information about that program.

DATES: Pre-applications are due by July 26, 2010, at 5 p.m. EDT, and applications must be submitted by August 23, 2010, at 5 p.m. EDT. Only pre-applications received and applications received through Grants.gov will be deemed properly filed. Instructions for submitting pre-applications and applications are included in Section VI.

FOR FURTHER INFORMATION CONTACT: For further information concerning this notice please contact the TIGER II Discretionary Grant program manager via e-mail at *TIGERIIGrants@dot.gov,* or call Robert Mariner at 202–366–8914 (this is not a toll-free number). A TDD is available for individuals who are deaf or hearing-impaired, at 202–366–3993 (this is not a toll-free number). In addition, DOT will regularly post answers to questions and requests for clarifications on DOT's Web site at *http://www.dot.gov/recovery/ost/TIGERII.* Questions regarding HUD's Community Challenge Planning Grant Program should be directed to *sustainablecommunities@hud.gov* or may be submitted through the *http://www.hud.gov/sustainability* Web site. HUD's contact person is Zuleika K. Morales-Romero, Office of Sustainable Housing and Communities, 451 Seventh Street, SW., Washington, DC 20410–3000, telephone number 202–402–7683 (this is not a toll-free number) facsimile 202–708–0465, or e-mail: *zuleika.k.morales@hud.gov.* For the hearing- or speech-impaired, contact the above telephone number via TTY by dialing the toll-free Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

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Overview Information

A. *Federal Agency Name:* Office of Sustainable Housing and Communities, Office of the Deputy Secretary, HUD; and Office of the Secretary, DOT.

B. *Funding Opportunity Title:* Community Challenge and Transportation Planning Grants.

C. *Funding Opportunity Number:* The funding opportunity number is FR–5415–N–12. Community Challenge and Transportation Planning Grant. The OMB Approval Number is 2501–0025.

D. *Catalog of Federal Domestic Assistance (CFDA) Number:* The Catalog of Federal Domestic Assistance (CFDA) numbers for the HUD Community Challenge and DOT TIGER II Planning Grant are 14.704 and 20.933, respectively.

E. *Additional Overview Information:*

1. Background.

a. *TIGER II Planning Grants.*

On February 17, 2009, the President signed the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–05) (Recovery Act), which appropriated $1.5 billion of discretionary grant funds to be awarded by DOT for capital investments in surface transportation infrastructure. DOT refers to these grants as Grants for Transportation Investment Generating Economic Recovery or "TIGER Discretionary Grants." DOT solicited applications for TIGER Discretionary Grants through a notice of funding availability published in the **Federal Register** on June 17, 2009 (74 FR 28775) (an interim notice was published on May 18, 2009 (74 FR 23226)). Applications for TIGER Discretionary Grants were due on September 15, 2009, and DOT received more than 1,400 applications with funding requests totaling almost $60 billion. Funding for 51 projects was announced on February 17, 2010.

On December 16, 2009, the President signed the Fiscal Year (FY) 2010 Consolidated Appropriations Act, which appropriated $600 million to DOT for National Infrastructure Investments using language that is similar, but not identical to, the language in the Recovery Act authorizing the TIGER Discretionary Grants. DOT is referring to the grants for National Infrastructure Investments as TIGER II Discretionary Grants. The FY 2010 Appropriations Act permits DOT to use up to $35 million of the funds available for TIGER II Discretionary Grants for TIGER II Planning Grants. The TIGER II Discretionary Grant NOFA was published on June 1, 2010 (75 FR 30460), and awards will be announced at the same time as awards made under this NOFA.

b. *Community Challenge Planning Grants.*

The FY 2010 Appropriations Act also appropriated $40 million to HUD to establish a Community Challenge Planning Grant Program "to foster reform and reduce barriers to achieve affordable, economically vital, and sustainable communities." The Community Challenge Planning Grant Program differs from HUD's Sustainable Communities Regional Planning Grant Program, a $100 million program also created in the FY 2010 Appropriations Act. While the latter program is designed to support regional planning efforts, the Community Challenge Planning Grant Program focuses on individual jurisdictions and more localized planning. HUD will publish a separate NOFA for the Sustainable Communities Regional Planning Grant Program.

2. *Available Funds.* Up to $75 million, including $40 million for Community Challenge Planning Grants and up to $35 million for TIGER II Planning Grants.

3. *Funding Categories.* Given the range of planning activities that potential applicants are trying to accomplish, DOT and HUD will support a variety of eligible activities spelled out in Section III.C.1.a–c.

4. *Authority.* The program was authorized by the Consolidated Appropriations Act, 2010 (Pub. L. 111–117, approved December 16, 2009).

5. *Application of HUD's General Section.* All applicants accessing resources available through HUD's Community Challenge Planning Grants are subject to the requirements of the General Section to HUD's FY 2010 NOFAs for discretionary programs. Applicants for such grants should carefully review the requirements described in this NOFA and HUD's General Section. HUD's General Section is not applicable to applicants accessing resources available through TIGER II Planning Grants.

Full Text Announcement

I. *Funding Opportunity Description:* This notice announces DOT's and HUD's intention to offer funding through a competition made available as a NOFA under its Community Challenge and TIGER II Planning Grants.

A. *The Partnership for Sustainable Communities.* This NOFA is being initiated in close coordination between DOT, HUD and the EPA, through the Partnership for Sustainable Communities (the Partnership).

The Partnership was conceived to coordinate Federal housing, transportation and environmental investments, protect public health and the environment, promote equitable development, and help address the challenges of climate change. Recognizing the fundamental role that public investment plays in achieving these outcomes, the Administration charged three agencies whose programs most directly impact the physical form of communities—HUD, DOT, and EPA—to lead the way in reshaping the role of the Federal government in helping communities obtain the capacity to embrace a more sustainable future.

One of the first acts of the Partnership was to agree to a set of six "Livability Principles" to govern the work of the Partnership and for each of the three agencies to strive to incorporate into their policies and funding programs to the degree possible. In addition, each agency has clear and defined roles: HUD will take the lead in funding, evaluating, and supporting integrated regional planning for sustainable development, and will invest in sustainable housing and community development efforts. DOT will focus on building the capacity of transportation agencies to integrate their planning and investments into broader plans and actions that promote sustainable development, and investing in transportation infrastructure that directly supports sustainable development and livable communities. EPA will provide technical assistance to communities and States to help them implement sustainable community strategies, and develop environmental sustainability metrics and practices. The three agencies have made a commitment to coordinate activities, integrate funding requirements, and adopt a common set of performance metrics for use by grantees.

B. *Program Goals.*

1. To better align Federal programs to support the building of projects that further the six Livability Principles (listed in rating factor 1 below).

2. To remove artificial or bureaucratic barriers among Federal programs and create a more coordinated point of contact for State and local governments building innovative projects that coordinate housing, economic

development, transportation, and environmental policies and goals.

II. Award Information

A. *Award Size.* For both Community Challenge Planning Grants and TIGER II Planning Grants, there is no minimum grant size, but the maximum grant size is $3 million.

B. *Type of Awards.* All awards will be made in the form of Cooperative Agreements. HUD and DOT anticipate having substantial involvement in the work being conducted under this award to ensure the purposes of the grant program are being carried out and that entities are following through on their commitments. This includes making progress in meeting established performance metrics, and ensuring consistency in projects in participating jurisdictions that are funded through other HUD, DOT, and EPA programs so that they are implemented in a manner consistent with the Livability Principles.

C. *Period of Performance.* The period of performance shall not exceed 36 months from the date the funds are obligated. All funds awarded must be obligated by September 30, 2012.

D. *Statutory Distributional Requirements Only Applicable to TIGER II Funds.* This joint notice was developed and is being published in conjunction with the TIGER II Discretionary Grants NOFA. The selection process for TIGER II Planning Grants will be conducted in parallel with the selection process for TIGER II Discretionary Grants, and awards of TIGER II Planning Grants are subject to several distributional requirements under the FY 2010 Appropriations Act. These requirements do not apply to HUD Community Challenge Planning Grants. First, no more than 25 percent of the funds made available for TIGER II Discretionary Grants (or $150 million), including any funding used for TIGER II Planning Grants, may be awarded to projects in a single State. Additionally, not less than $140 million of the funds provided for TIGER II Discretionary Grants, including TIGER II Planning Grants, is to be used for projects located in rural areas. For purposes of this notice, DOT is generally defining "rural area" as any area not in an Urbanized Area, as such term is defined by the Census Bureau[1] and will consider a project to be in a rural area if all or the majority of a project is located in a rural area. Finally, on awarding TIGER II Discretionary Grants, including TIGER II Planning Grants, DOT must take measures to ensure an equitable geographic distribution of grant funds, an appropriate balance in addressing the needs of urban and rural areas, and investment in a variety of transportation modes.

TIGER II Discretionary Grants, including TIGER II Planning Grants, may be used for up to 80 percent of the costs of a project; however, applications will be more competitive to the extent they include significant non-Federal financial contributions. The minimum and maximum grant sizes established by the FY 2010 Appropriations Act for TIGER II Discretionary Grants do not apply to TIGER II Planning Grants.

III. Eligibility Information

A. *Eligible Applicants.* State and local governments, including U.S. territories, tribal governments, transit agencies, port authorities, metropolitan planning organizations (MPOs), other political subdivisions of State or local governments, and multi-State or multijurisdictional groupings.

B. *Cost Sharing or Leveraging Resources.* For those seeking TIGER II Planning Grants, a 20 percent match is required. DOT will consider any non-Federal funds as a local match for purposes of this program, whether such funds are contributed by the public sector (State or local) or the private sector. However, DOT will not consider funds already expended as a local match. The 20 percent matching requirement does not apply to projects in rural areas. For those seeking HUD Community Challenge Planning Grants, applicants must provide 20 percent of the requested funding amount in leveraged resources in the form of cash and/or verified in-kind contributions or a combination of these sources. In-kind contributions may be in the form of staff time, donated materials, or services. All assistance provided to meet this requirement must be identified by their dollar equivalent based upon accepted salary or regional dollar values. Cash contributions may come from any combination of local, state and/or Federal funds, and/or private and philanthropic contributions dedicated to the express purposes of this proposal.

Applicants will receive credit for leveraging or matching resources greater than 20 percent of the requested amount as described in Rating Factor 4. If an applicant does not include the minimum 20 percent leveraged or matched resources with its appropriate supporting documentation, that application will be considered ineligible.

C. *Other Requirements.*

1. *Eligible Activities.* In order to explain the variety of activities eligible for funding under this joint notice, the activities are described in three groupings:

a. *TIGER II Planning Grants:* Activities related to the planning, preparation, or design of surface transportation projects, including, but not limited to:

(1) Highway or bridge projects eligible under Title 23, United States Code;

(2) Public transportation projects eligible under Chapter 53 of Title 49, United States Code;

(3) Passenger and freight rail transportation projects; and

(4) Port infrastructure investments.

b. *Community Challenge Planning Grants:* Activities related to the following:

(1) Development of master plans or comprehensive plans that promote affordable housing co-located and/or well-connected with retail and business development and discourage development not aligned with sustainable transportation plans or disaster mitigation analyses;

(2) Development and implementation of local, corridor or district plans and strategies that promote livability and sustainability (see the Livability Principles in Section V);

(3) Revisions to zoning codes, ordinances, building standards, or other laws to remove barriers and promote sustainable and mixed-use development and to overcome the effects of impediments to fair housing choice in local zoning codes and other land use laws, including form-based codes and inclusionary zoning ordinances to promote accessible, permanently affordable housing that reduces racial and poverty housing concentration and expands fair housing choice for low-income minorities;

(4) Revisions to building codes to promote the energy-efficient rehabilitation of older structures in order to create affordable and healthy housing;

(5) Strategies for creating or preserving affordable housing for low-, very low-, and extremely low-income families or individuals in mixed-income, mixed-use neighborhoods along an existing or planned transit corridor;

(6) Strategies to bring additional affordable housing to areas that have few affordable housing opportunities and are close to suburban job clusters; and

[1] For the 2000 Census, the Census Bureau defined an Urbanized Area (UA) as an area that consists of densely settled territory that contains 50,000 or more people. Updated lists of UAs are available on the Census Bureau Web site. Urban Clusters (UCs) will be considered rural areas for purposes of this NOFA.

(7) Planning, establishing, and maintaining acquisition funds and/or land banks for development, redevelopment, and revitalization that reserve property for the development of affordable housing within the context of sustainable development

c. *Combination of TIGER II Planning Grant and Community Challenge Planning Grant activities.* There are a variety of projects that may include eligible activities under both the TIGER II Planning Grants and the Community Challenge Planning Grants programs. Rather than have applicants proceed through two separate grant application procedures, this joint NOFA is intended to create one point of entry to Federal resources to support related components of a single project. To illustrate the possible combination of activities, please consider the following examples:

(1) Planning activities related to the development of a particular transportation corridor or regional transportation system, that promotes mixed-use, transit-oriented development with an affordable housing component.

(2) Planning activities related to the development of a freight corridor that seeks to reduce conflicts with residential areas and with passenger and non-motorized traffic. In this type of project, DOT might fund the transportation planning activities along the corridor, and HUD may fund changes in the zoning code to support appropriate siting of freight facilities and route the freight traffic around town centers, residential areas, and schools.

(3) Developing expanded public transportation options, including accessible public transportation and para-transit services for individuals with disabilities, to allow individuals to live in diverse, high opportunity neighborhoods and communities and to commute to areas with greater employment and educational opportunities.

DOT and HUD are expecting to award the TIGER II Planning Grants and the Community Challenge Planning Grants for planning activities that ultimately lead to the development of projects that integrate transportation, housing and economic development components.

DOT and HUD plan to make joint awards, where appropriate. However, we also expect DOT to make awards for TIGER II Planning Grant activities alone and for HUD to make awards for Community Challenge Planning Grants alone. Applicants may apply for funding from only TIGER II Planning Grants or from only Community Challenge Planning Grants. To the extent that an application has a project that has linked activities and would benefit from funding and associated activities in both DOT and HUD's programs, applicants should indicate that in their application and the agencies may both award funding to the project, with DOT and HUD each awarding its funds for the eligible activities under its own respective program. However, only one application per project will be accepted (see Threshold Requirements, Section IV.C.).

IV. Threshold Requirements

Evaluation teams from DOT and HUD will review each pre-application that is received on or prior to the Pre-Application Deadline and will be responsible for analyzing whether the pre-application satisfies the following key threshold requirements:

A. The project and the applicant are eligible for funding under the TIGER II Planning Grant or Community Challenge Planning Grant program; and

B. Local leveraging, or matching funds are committed to support 20 percent or more of the costs of the transportation planning activities to be funded; this requirement is not applicable to transportation planning projects located in rural areas.

C. Only one application per project will be accepted for review. An applicant that submits more than one application per project may have some or all of the submissions deemed ineligible.

D. Resolution of Outstanding Civil Rights Matters for Applicants for HUD Funding. If you, the applicant:

1. Have received a charge from HUD concerning a systemic violation of the Fair Housing Act or a cause determination from a substantially equivalent state or local fair housing agency concerning a systemic violation of a substantially equivalent state or local fair housing law proscribing discrimination based on race, color, religion, sex, national origin, disability or familial status;

2. Are a defendant in a Fair Housing Act lawsuit filed by the Department of Justice alleging a pattern or practice of discrimination pursuant to 42 U.S.C. 3614(a);

3. Have received a letter of findings identifying systemic noncompliance under Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, or Section 109 of the Housing and Community Development Act of 1974;

4. Have received a cause determination from a substantially equivalent state or local fair housing agency concerning a systemic violation of provisions of a state or local law proscribing discrimination in housing based on sexual orientation or gender identity; or

5. Have received a cause determination from a substantially equivalent state or local fair housing agency concerning a systemic violation of a state or local law proscribing discrimination in housing based on lawful source of income; and

a. The charge, cause determination, lawsuit, or letter of findings referenced in subparagraphs (1), (2), (3), (4), or (5) above has not been resolved to HUD's satisfaction before the application deadline, then you, the applicant, are ineligible for funding. HUD will determine if actions to resolve the charge, cause determination, lawsuit, or letter of findings taken before the application deadline are sufficient to resolve the matter.

b. Examples of actions that would normally be considered sufficient to resolve the matter include, but are not limited to:

c. Current compliance with a voluntary compliance agreement signed by all the parties;

(1) Current compliance with a HUD-approved conciliation agreement signed by all the parties;

(2) Current compliance with a conciliation agreement signed by all the parties and approved by the State or local administrative agency with jurisdiction over the matter;

(3) Current compliance with a consent order or consent decree; or

(4) Current compliance with a final judicial ruling or administrative ruling or decision.

V. Application Review Information

A. *Criteria.*

1. *Rating Factor 1—Purpose and Outcomes (35 points):* An applicant's score on this rating factor will be based on a clear statement of the existing condition that the proposed project is intended to address and the proposed project's alignment with the six "Livability Principles." Applicants that demonstrate that their project aligns well with the Livability Principles and are consistent with any existing region wide plans that consider transportation, economic development, housing, water, and other infrastructure needs and investments will receive a higher score. The Livability Principles are as follows:

a. *Provide More Transportation Choices.* Develop safe, reliable and affordable transportation choices to decrease household transportation costs, reduce energy consumption and dependence on foreign oil, improve air quality, reduce greenhouse gas emissions, and promote public health.

b. *Promote equitable, affordable housing.* Expand location- and energy-efficient housing choices for people of all ages, incomes, races, and ethnicities to increase mobility and lower the combined cost of housing and transportation.

c. *Enhance Economic Competitiveness.* Improve economic competitiveness through reliable and timely access to employment centers, educational opportunities, services and other basic needs by workers, as well as expanded business access to markets.

d. *Support Existing Communities.* Target Federal funding toward existing communities—through strategies like transit oriented, mixed-use development, and land recycling—to increase community revitalization and the efficiency of public works investments and safeguard rural landscapes.

e. *Coordinate Policies and Leverage Investment.* Align Federal policies and funding to remove barriers to collaboration, leverage funding, and increase the accountability and effectiveness of all levels of government to plan for future growth, including making smart energy choices such as locally generated renewable energy.

f. *Value Communities and Neighborhoods.* Enhance the unique characteristics of all communities by investing in healthy, safe, and walkable neighborhoods—rural, urban, or suburban.

In order for points to be awarded, applicants shall also provide data to support outcomes of the proposed project claimed in the application. Based on the project being proposed, the applicant shall identify the Livability Principle(s) that will be addressed and detail how that success will be documented. For example, if the proposed program intends to expand the presence of equitable, affordable housing, the applicant should provide data to support this claim.

As there is a wide range of projects that can be supported through this notice, not every project is expected to address all six Livability Principles. Points will be awarded based on the extent to which the proposed project furthers the specifically identified principles supported with data.

The applicant is required to clearly identify the benefits or outcomes of its proposed program. Because this application seeks support to develop a plan for a specific project, all of the outcomes will not be realized during the duration of the grant period. Rather, applicants will be evaluated on their ability to identify the outcomes they seek to achieve, the clarity with which they articulate the elements of their plan that will help achieve those outcomes, and the specificity of the benchmarks that they establish to measure progress toward a completed product that guides all of the necessary work.

Applicants that receive awards will be expected to report on the progress of the project and outcomes realized at the mid-way point and at the end of the term of the grant. Where outcomes have been realized, they should be detailed and backed with data. For projects that must go to construction for many benefits to be realized, benchmarks will focus more on the progress of plan development, any changes in the scope of the work that occur during the planning process, and how those changes might impact the anticipated outcomes.

For projects that must go to construction for benefits to be realized, benchmarks will focus more on the progress of plan development, any changes in scope that occur, and how those changes might impact the anticipated outcomes.

DOT and HUD recognize that each project is unique. As such, the agencies are allowing significant latitude to the applicant to set the desired outcomes that will result from implementation of the project. DOT and HUD have identified six possible outcomes, listed below, from which each applicant must select a minimum of two outcomes that it must pursue and report on during its period of performance.

a. Travel changes, such as changes in mode share or vehicle miles traveled per capita.

b. Impact on affordability and accessibility, including the supply of affordable housing units, household transportation costs, or proportion of low- and very-low income households within a 30-minute transit commute of major employment centers.

c. Economic development, including infill development or recycled parcels of land or private sector investment along a project or corridor.

d. Improvement to the state of repair of infrastructure.

e. Environmental benefits, such as greenhouse gas or criteria pollutants emissions, oil consumption and recreational areas or open space preserved.

f. Increased participation and decision-making in developing and implementing a plan, code, development strategy, or project by populations traditionally marginalized in public planning processes.

2. *Rating Factor 2—Work Plan (35 points):* An applicant's score on this rating factor will be based on how well the application addresses the quality and cost effectiveness of the proposed work plan. Applicants must develop a work plan that includes specific deliverables, and measurable, time-phased objectives for each major activity.

This factor also addresses the performance metrics that will be used to measure the success of the proposed activities. For a proposed project to achieve results, expected outcomes and outputs must be clearly defined, and evaluation must take place to ensure that those outcomes and outputs are met. Outcomes are the ultimate objectives of a project, and outputs are the interim activities or products that lead to the achievement of those objectives. To track progress toward the outputs and outcomes, a project must be evaluated based upon performance measures. Performance measures should be objectively quantifiable, and allow one to assess the degree of actual achievement against the expected outputs and outcomes. Applications that demonstrate how outputs and outcomes are fully defined and easily measured will receive a higher score.

The applicant's budget proposal should thoroughly estimate all applicable costs (direct, indirect, and administrative), and be presented in a clear and coherent format. The applicant must thoroughly document and justify all budget categories, costs, and all major tasks, for the applicant, sub-recipients, joint venture participants, or other contributing resources to the project.

3. *Rating Factor 3—Leveraging and Collaboration (15 points):* An applicant's score on this rating factor will be based on how well the application demonstrates the project's ability to obtain other community, local, State, private, and Federal support, as applicable, and resources that can be combined with DOT and HUD program resources to achieve program objectives. Resources may include cash or in-kind contributions of services, equipment, or supplies allocated to the proposed program. In evaluating this factor, HUD and DOT will consider the extent to which the applicant has established working partnerships with other entities to get additional resources or commitments to increase the effectiveness of the proposed program activities.

When evaluating this factor, HUD and DOT will take into account two considerations: the amount of resources leveraged or matched that exceeds the required 20 percent, and per capita income in the applicable jurisdiction relative to the metropolitan average.

Data must be provided for the indicator when responding to this rating factor. The 20 percent of leveraged or matched resources that are a threshold requirement will not count as points toward this rating factor. To score points in this rating factor, resources may be provided by governmental entities, public or private organizations, and other entities. Other resources from the private sector or other sources committed to the program that exceed the required 20 percent leveraged or matched resources will be given extra weight for this rating factor. The applicant should provide supporting documentation of all committed funds. Please refer to Section VI., Application and Submission, for more details.

4. *Rating Factor 4—Capacity (15 points):* An applicant's score on this rating factor will be based on how well the application demonstrates the applicant's capacity to successfully implement the proposed activities in a timely manner. The applicant will provide specific examples of previous projects similar to the proposed effort that demonstrate its capacity to implement the proposed work plan. DOT and HUD will give priority to applications that demonstrate the prior experience to bring this type of project(s) that is the subject of the planning activities to completion. Priority will also be given to applications that demonstrate strong collaboration among a broad range of participants, including public, private and nonprofit entities.

The applicant shall designate the staff that is anticipated to manage the proposed project, as well as other staff anticipated to contribute to the project's completion. Ratings under this factor are based on the capacity of the applicant's organization, and its team, as applicable, and should include an assessment of the capacity of sub-contractors, consultants, sub-recipients, community-based organizations, and any other entities that are part of the project application, as applicable.

Applicants should be prepared to initiate eligible activities within 120 days of the effective date of the grant award. DOT and HUD reserve the right to terminate the grant if sufficient personnel or qualified experts are not retained within these 120 days. In rating this factor, DOT and HUD will consider, among other factors, the extent to which the application demonstrates that the applicant has an adequate number of key staff or the ability to procure individuals with the knowledge and recent experience in the proposed activity.

All applicants for HUD funding are subject to the requirements to Affirmatively Further Fair Housing. HUD will award additional points to applicants that prioritize additional measures to advance civil rights, such as Executive Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, and Executive Order 13166, Improving Access to Services for Persons with Limited English Proficiency.

Applicants should indicate if, and describe how, the following policy priorities will be addressed: (1) Capacity Building and Knowledge Sharing and (2) Expand Cross-Cutting Policy Knowledge. One point will be awarded for each policy priority. Identify specific activities, outputs and outcomes that further these policy priorities over the period of performance.

a. *Capacity Building and Knowledge Sharing.*

HUD recognizes that successful program implementation can only occur in partnership with effectively prepared grantees. It is therefore critical to strengthen the capacity of each consortium by developing partnerships that will advance the objectives of proposed programs. HUD's Strategic Plan emphasizes the importance of strengthening the capacity of state and local partners to implement HUD programs, participate in decision-making and planning processes, and coordinate on cross-programmatic, place-based approaches through grant making and technical assistance. To receive policy priority points, applicants are expected to describe how they will achieve the following outcomes:

(1) Increase the skills and technical expertise of partner organizations to manage Federal awards, provide solid financial management, and perform program performance assessment and evaluation. The applicant must describe the methods that will be used to achieve this outcome. Examples include in-service trainings, online information provision (*e.g.,* webinars, podcasts, *etc.*), and structured observation of best practices. According to the proposed methods, the applicant should identify the anticipated outputs (*e.g.,* number of people trained, number of training events, volume of easily accessible training materials for targeted capacities, *etc.*) during the 3-year period of performance.

(2) Share knowledge among partners so that key personnel responsible for grant implementation coordinate cross-programmatic, placed-based approaches. The applicant must describe the outreach methods that will be used to achieve this outcome. Examples include establishing regular partner dialogues, and structured peer exchange. According to the proposed methods, the applicant should establish and specify the anticipated outputs (*e.g.,* number of meetings, Web postings, number of participating partners, total staff exposed to new learning and promising practice, number of briefings, issuance of monthly fact sheets, *etc.*) during the 3-year period of performance. HUD will work with grantees to support knowledge sharing and innovation by disseminating best practices, encouraging peer learning, publishing data analysis and research, and helping to incubate and test new ideas.

b. *Expand Cross-Cutting Policy Knowledge.*

Broadening the use of successful models to other communities requires definitive evidence of which policies work and how, and a plan for public dissemination of this information.

To achieve full points, the applicant must indicate what data they and/or partner organizations will collect on outcomes for the defined target area (*e.g.,* changes in commuting time, improved health outcomes, VMT measures, *etc.*). The grantee must document a plan to engage credible policy researchers to assist in the analysis of that data in order to measure policy impact, and clarify the extent of data that will be made available to those researchers through a data-sharing agreement.

(1) For household-level data, this may be an agreement with a university or other policy research group that regularly produces peer-reviewed research publications.

(2) For parcel-related data, this agreement may be with a regional planning, non-profit, or government agency that provides consolidated local data on a regular basis to the public for free.

The applicant should specifically describe how they intend to disseminate policy lessons learned during the planning process to a diverse range of potential audiences, including policymakers, other regional consortia, and interested community leadership. The collection method and specific data elements will not be prescribed by HUD, but may be determined by the applicant.

The applicant must establish and provide the anticipated outputs within the period of performance. Examples include the number of policy publications, number of research studies, anticipated distribution of findings, etc.

B. *Evaluation and Selection Process.*

1. *Rating and Ranking.*

Evaluation teams made up of a representative from DOT, HUD, and EPA initially will evaluate each application as to how well it scores against the "Rating Factors" identified below, and will assign it a score on a scale of 1–100. The scoring system will not determine the specific projects that will be selected for funding; rather, the scoring system will be used to generate a list of highly recommended projects. The highly recommended projects will then be forwarded to a senior-level review team for review, and the senior-level review team will make funding recommendations to the Secretaries of DOT and HUD, based on how the project performed under the four rating factors, how each project addresses the Program Goals identified in Section I.B, and statutory distributional considerations required in the National Infrastructure Investments provision of the FY 2010 Consolidated Appropriations Act for the DOT Planning Grants. The review teams will include senior-level representatives from the three Partnership for Sustainable Communities agencies: DOT, HUD, and EPA.

VI. Application and Submission Information

A. *Address To Request Application Package.* Applications are available on the Federal Web site *www.Grants.gov*. To find this funding opportunity at Grants.gov, go to *http://www.grants.gov/applicants/find_grant_opportunities.jsp* at the *www.Grants.gov* Web site, where you can search by agency and/or perform a Basic Search. Additional information on applying through Grants.gov is available at *http://www.grants.gov.*

B. *Content and Form of Application Submission.* Applicants eligible to apply under this NOFA are to follow the submission requirements described below:

1. *Pre-Application.* Unless otherwise indicated in this joint notice, applicants should submit pre-applications and applications in accordance with the procedures specified in the TIGER II Discretionary Grant NOFA. To submit an application, please access *http://www.dot.gov/recovery/ost/tigerii/index.html* or *http://www.hud.gov/sustainability.* Pre-applications must be submitted by the Pre-Application Deadline, which is July 26, 2010, at 5 p.m. EDT. The pre-application system will be hosted by DOT, on behalf of DOT and HUD, and will open no later than June 23, 2010, to allow prospective applicants to submit pre-applications. Final applications must be submitted through Grants.gov by the Application Deadline, which is August 23, 2010, at 5 p.m. EDT. The Grants.gov "Apply" function will open on July 30, 2010, allowing applicants to submit applications. While applicants are encouraged to submit pre-applications in advance of the Pre-Application Deadline, pre-applications will not be reviewed until after the Pre-Application Deadline. Similarly, while applicants are encouraged to submit applications in advance of the Application Deadline, applications will not be evaluated until after the Application Deadline. Awards will not be made until after September 15, 2010.

To apply for funding through Grants.gov, applicants must be properly registered. Complete instructions on how to register and submit applications can be found at *www.grants.gov.* Please be aware that the registration process usually takes 2–4 weeks and must be completed before an application can be submitted. If interested parties experience difficulties at any point during the registration or application process, please call the toll free Grants.gov Customer Support Hotline at 1–800–518–4726, Monday to Friday from 7 a.m. to 9 p.m. EDT.

Applicants must submit a pre-application as Stage 1, which qualifies applicants to submit an application in Stage 2. An application submitted during Stage 2 that does not correlate with a properly completed Stage 1 pre-application will not be considered.

2. *Contents of Pre-Applications.* An applicant for a TIGER II Planning Grant or a Community Challenge Planning Grant should provide in its pre-application form, all of the information requested below in its pre-application form. DOT and HUD reserve the right to ask any applicant to supplement the data in its pre-application but expect pre-applications to be complete upon submission. Applicants must complete the pre-application form and submit it electronically on or prior to the Pre-Application Deadline, in accordance with the instructions specified at *http://www.dot.gov/recovery/ost/TIGERII.* The pre-application form must include the following information:

a. Name of applicant (if the application is to be submitted by more than one entity, a lead applicant must be identified);

b. Applicant's DUNS (Data Universal Numbering System) number;

c. Type of applicant (State government, local government, U.S. territory, Tribal government, transit agency, port authority, metropolitan planning organization, or other unit of government);

d. State(s) where the project is located;

e. County(s) where the project is located;

f. City(s) where the project is located;

g. Zip code(s) where the project is located;

h. Project title (descriptive);

i. Project type: specify eligible activities proposed for funding, such as transportation planning activity, site area plan, corridor plan, land assembly or acquisition, etc.;

j. Project description: describe the project in plain English terms that would be generally understood by the public, using no more than 50 words; this should be purely descriptive, not a discussion of the project's benefits, background, or alignment with the selection criteria in this description;

k. Total cost of the project;

l. Total amount of TIGER II Planning Grant and Community Challenge Planning Grant funds requested;

m. Contact name, telephone number, email address, and physical address of the applicant;

n. Type of jurisdiction where the project is located (urban or rural); and

o. An assurance that local matching funds are committed to support 20 percent or more of any transportation planning activities to be funded. (This requirement does not apply to projects located in rural areas).

3. *Applications.* An application for a TIGER II Planning Grant or a Community Challenge Planning Grant should include all of the information requested below. DOT and HUD reserve the right to ask any applicant to supplement the data in its application, but expect applications to be complete upon submission.

a. *Standard Form SF–424, Application for Federal Assistance.* Please see *www07.grants.gov/assets/SF424Instructions.pdf* for instructions on how to complete the SF–424, which is part of the standard Grants.gov submission. Additional clarifying guidance and Frequently Asked Questions (FAQs) to assist applicants in completing the SF–424 will be available at *http://www.dot.gov/recovery/ost/TIGERII* by July 30, 2010, when the "Apply" function within Grants.gov opens to accept applications under this notice.

b. *In Responding to the First and Second Rating Factor.* (Attachment to SF–424). A TIGER II Planning Grant and HUD Community Challenge Grant application must include information required for DOT and HUD to assess each of the rating factors specified in Section III (Application Review and Rating Factors). Applicants are

encouraged to demonstrate the responsiveness of a project to any and all of the rating factors with the most relevant information that applicants can provide, regardless of whether such information has been specifically requested, or identified, in this notice.

In order to fulfill the requirements of the first rating factor, an applicant must:

(1) Submit a narrative describing how the applicant will use the funding sought to achieve its desired outcomes and how the desired outcomes support the six Livability Principles. The narrative should also state the problems or barriers the project seeks to address, why they are an impediment to promoting a more sustainable future for the applicant community, and the outcomes the project seeks to achieve.

(2) Submit data supporting any assertions made about the expected outcomes, as well as the nature and the extent of the problems or barriers the project seeks to remove.

In responding to the second rating factor, applicants must provide a narrative to discuss their project outcomes, outputs, and performance measures. Applicants should also identify important milestones (*e.g.,* the end of specific phases in a multiphase project), which should also be clearly indicated in the proposal timeline. Applicants should also identify potential obstacles in meeting outcomes and outputs and related performance measures and discuss steps they would take to respond to these obstacles. Finally, applicants should describe how project evaluation information will be obtained, documented, and reported.

Applicants should submit a work plan that includes the following:

(1) Proposed Activities. Briefly describe the overall activity you propose to undertake, including any coordinated components that will not be directly funded under the TIGER II Planning Grant Program or the Community Challenge Planning Grant Program. Describe the regional or local significance of the project and whether it is a part of a comprehensive regional plan. Include public outreach and participation activities, including minority and disadvantaged populations.

(2) Uses of Funds/Budget. Indicate how you will use the grant funds you are seeking by providing a list or table showing the amount of funds budgeted for each activity you will undertake to achieve your desired result. Indicate the entity responsible for each use and activity, including any elected bodies or bodies appointed by elected officials. Specify administrative costs.

(3) Project Completion Schedule. Briefly describe the project completion schedule, including milestones in each month for the critical management actions for you and any other entity whose cooperation or assistance is necessary to achieve your desired result, including the end dates of each required action and your expected metrics and results.

(4) Performance Measures. List the performance measures you will use to evaluate the success of your project or activity, as well as the benchmarks you expect to reach during the term of the grant and a timeline for reaching them.

c. *In Responding to the Third Rating Factor.* Applicants will not receive full points if they do not submit evidence of a firm commitment and the appropriate use of leveraged or matched resources under the grant program. Such evidence must be provided in the form of letters of firm commitment, memoranda of understanding, or other signed agreements to participate from those entities identified as partners in the application. Each letter of commitment, memorandum of understanding, or agreement to participate should include the organization's name, the proposed level of commitment, and the organization's responsibilities as they relate to the proposed project. The commitment must be signed and dated by an official of the organization legally able to make commitments on behalf of the organization. Applicants should describe how they will ensure that commitments to sub-grantees will be honored and executed, contingent upon an award from DOT or HUD.

(1) Applicants must support each source of contributions, cash or in-kind, both for the required minimum and additional amounts, by a letter of commitment from the contributing entity, whether a public or private source. The letter must describe the contributed resources that you will use in the program and their designated purpose. Staff in-kind contributions should be given a monetary value based on the local market value of the staff skills. If you do not provide letters from contributors specifying details and the amount of the actual contributions, those contributions will not be counted.

d. *In Responding to the Fourth Rating Factor.* DOT and HUD will consider how the applicant entity is organized and how it will function in implementing the grant. The application should include a description of the leadership responsibilities and procedures for allocating resources, setting goals, and settling disputes. It should also include an explanation of the capacity and relevant, recent experience of the applicant entity. The application should also include a description of the applicant's experience in outreach efforts involving low-income persons, particularly those living in revitalization areas where funds are proposed to be used, residents of public housing, minorities, socially and economically disadvantaged individuals, non-English speaking persons, and persons with disabilities.

Applicants should demonstrate that they either have sufficient personnel or the ability to procure qualified experts or professionals, with the knowledge, skills, and abilities with relevant experience to carry out the proposed activity.

Contact information is requested as part of the SF–424. This information will be used in order to inform parties of the selection of projects for funding, as well as to contact parties in the event additional information is needed.

e. *Page Limit.* Applications should be limited to a total of 15 pages. HUD and DOT will not refer to Web sites for information pertinent to the narrative response. All applications should include a detailed description of the proposed project and geospatial data for the project, including a map of the area to be planned and where other work will occur.

C. *Submission Dates and Times.* All pre-applications must be submitted in accordance with the instructions specified at *http://www.dot.gov/recovery/ost/TIGERII.* The pre-application system will be hosted by DOT, on behalf of DOT and HUD. Final applications must be submitted electronically through Grants.gov. Pre-applications are due by July 26, 2010, at 5 p.m. EDT, and applications must be submitted by August 23, 2010, at 5 p.m. EDT.

D. *Funding Restrictions.* Applicants should also be aware that DOT is accepting applications for capital expenditures associated with surface transportation projects in the TIGER II Discretionary Grant notice (Docket No. DOT–OST–2010–0076). As part of that program, applicants may request planning funds associated with their capital request. If DOT awards planning funding to an applicant to the TIGER II Discretionary Grant program, the funding available through this notice will be lessened by that amount. Further, DOT has the option to use less than the $35 million permitted in the statute and may do so based on distributional requirements or the need to fund highly recommended capital grant applications.

VII. Award Administration Information

A. *Award Notices.*

1. *Applicants Selected for Award.* Projects selected for a TIGER II Planning Grant will be administered by one of DOT's modal administrations, pursuant to a grant agreement between the TIGER II Planning Grant recipient and the DOT modal administration.

HUD awardees will be required to negotiate a final statement of work and will enter into a Cooperative Agreement with HUD. The Cooperative Agreement will also contain an agreed upon Logic Model identifying specific activities and performance criteria to be reported against over a period of time. HUD grantees must meet the requirements contained in the General Section to HUD's FY 2010 Funding Notices.

2. *Adjustment of Funding.* DOT and HUD reserve the right to fund less than the full amount requested in an application based on the availability of funds, geographic diversity, and to ensure that the maximum number of grants may be made.

3. HUD grant recipients must comply with applicable Federal requirements, including compliance with the Fair Housing and Civil Rights Laws applicable to all Federal awards.

B. *Administrative and National Policy Requirements.*

1. *Environmental Requirements.* All applicants that are proposing to use grant funds for land acquisition must comply with HUD's environmental procedures. In accordance with 24 CFR 50.19(b)(1), (9), and (16), all other eligible activities assisted by HUD funds under this NOFA are categorically excluded from environmental review under the National Environmental Policy Act of 1969 and are not subject to environmental review under the related laws and authorities. For applicants requesting grant funds for transportation planning, NEPA is not typically triggered (and even if triggered, categorical exclusions typically exist). However, if any projects planned with funding under this NOFA move to the construction phase and Federal funds are later sought for construction, all appropriate NEPA analyses will need to be completed prior to any Federal expenditures.

Under HUD's environmental procedures, for those applications involving land acquisition activities requiring environmental review, the notification of award to a selected applicant will constitute a preliminary approval by HUD, subject to the completion of an environmental review of the proposed site(s), and the execution by HUD and the recipient of a Grant Agreement. Selection for participation (preliminary approval) does not constitute approval of the proposed site(s). Each proposal will be subject to a HUD environmental review, in accordance with 24 CFR part 50, and the proposal may be modified or the proposed sites rejected as a result of that review.

Submission of an application involving a project requiring an environmental review will constitute an assurance that the applicant shall assist HUD in complying with 24 CFR part 50 and shall:

(1) Supply HUD with all available, relevant information necessary for HUD to perform for each property any environmental review required by 24 CFR part 50;

(2) Carry out mitigating measures required by HUD or select alternate eligible property; and

(3) Not acquire, rehabilitate, demolish, convert, lease, repair, or construct property, nor commit or expend HUD or local funds for these program activities with respect to any eligible property, until HUD approval of the property is received.

For assistance, contact the HUD Environmental Review Officer in the HUD Field Office serving your area.

Contact information is requested as part of the SF–424. DOT will use this information to inform parties of DOT's decision regarding selection of projects, as well as to contact parties in the event that DOT needs additional information about an application.

2. *Administrative and Indirect Cost Requirements.* For reference to the Administrative Cost requirements and Indirect cost requirements, please see OMB Circulars A–21, A–87, and A–122, as applicable.

C. *Reporting Requirements.* HUD Award Agreements will include the terms and conditions of the award including the reporting requirements.

1. Final Work Plan and Logic Model. Final work plan and completed Logic Model are due 60 days after the effective date of the grant agreement. See the General Section for detailed information on the use of the "Master" eLogic Model.

2. Successful applicants will be required to submit bi-annual and final program reports according to the requirements of the award agreement. Your bi-annual and final report must include a completed Logic Model, form HUD–96010, *approved and incorporated into your award agreement,* showing specific outputs and outcome results against those proposed and accepted as part of your approved grant agreement.

3. Financial reporting requirements include, but are not limited to, the submission of the financial status report, SF–425, bi-annually.

VIII. Other Information

A. Compliance with Fair Housing and Civil Rights Laws and Affirmatively Furthering Fair Housing for Community Challenge Planning Grant Applicants

Fair Housing and Civil Rights Laws:

1. With the exception of Federally recognized Indian tribes and their instrumentalities, applicants and their sub-recipients must comply with all applicable fair housing and civil rights requirements in 24 CFR 5.105 (a), including, but not limited to, the Fair Housing Act, Title VI of the Civil Rights Act of 1964, and the Rehabilitation Act of 1973.

2. If you are a federally recognized Indian tribe, you must comply with the nondiscrimination provisions enumerated at 24 CFR 1000.12, as applicable. See the General Section for further instructions on this requirement.

3. *Affirmatively Furthering Fair Housing:* Section 808(e)(5) of the Fair Housing Act imposes a duty on HUD to affirmatively further the purposes of the Fair Housing Act in its housing and urban development programs. This obligation further applies generally to recipients of HUD funds, including those awarded and announced under HUD's FY 2010 funding notices. Your application must include a discussion on how your proposed plans affirmatively further fair housing; applications that include specific activities and outcomes that address this requirement will be rated higher. Applicants for Community Challenge Planning Grants that are tribal governments are not subject to the affirmatively furthering fair housing submission requirement in the General Section.

B. *Additional Environmental Requirements.* A Finding of No Significant Impact (FONSI) with respect to the environment has been made for this NOFA in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The FONSI is available for public inspection between 8 a.m. and 5 p.m. weekdays in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 10276, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, an advance appointment to review the FONSI must

be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number).

Dated: June 18, 2010.

Ray LaHood,

Secretary, Department of Transportation.

Shaun Donovan,

Secretary, Department of Housing and Urban Development.

[FR Doc. 2010–15353 Filed 6–21–10; 4:15 pm]

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S. 3473/P.L. 111–191
To amend the Oil Pollution Act of 1990 to authorize advances from Oil Spill Liability Trust Fund for the Deepwater Horizon oil spill. (June 15, 2010; 124 Stat. 1278)
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